NUTRITION & FOOD INNOVATION UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 154th MEETING – OPEN TO OBSERVERS

Held on 30 November 2022, TELE/WEB

(Agreed on 16 December 2022)

Participants

- Panel Members:

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

- European Commission:

DG SANTE:

Juliette-Marie Margueritte and Olga Orlova

- EFSA

NIF Unit:

Ana Afonso, Michele Ardizzone, Giacomo De Sanctis, Silvia Federici, Antonio Fernández Dumont, Andrea Gennaro, Tilemachos Goumperis, Paschalina Grammatikou, Dafni Maria Kagkli, Paolo Lenzi, Aleksandra Lewandowska, Ana Martin Camargo, Franco Maria Neri, Nikoletta Papadopoulou, Pietro Piffanelli, Tommaso Raffaello, Reinhilde Schoonjans and Kyriaki Xiftou

MESE Unit:

Jose Ángel Gómez Ruiz

- Observers:

Adinda De Schrijver (Sciensano), Andreea Ona (University of Agricultural Sciences and Veterinary Medicine Cluj-Napoca), Anna Soyk (Rifcon GmbH), Cecilia Primo Planta (Syngenta), Christina Behr (Rifcon GmbH), Esteban Alcalde (Syngenta), Eva Priesnitz (Robert-Koch-Institute), Eytan Meisels (Huminn), Hanne Decuipere (Bayer CropScience), Holger Bartsch (SCC – Scientific Consulting Company – GmbH), Huixin Lin (Bayer), Ine Criel (BASF), Jelka Zabavnik Piano (University of Ljubljana), Lars Wiebrock (Chr. Hansen GmbH), Liudmyla Ishchenko (National University of Life and Environmental Sciences of Ukraine), Maica Martinez (BASF), Marisa Ingrosso (La Gazzetta del Mezzogiorno), Marjan Bovers (COGEM), Nancy Podevin (Corteva Agriscience), Natalija Atanasova-Pancevska (Faculty of Natural Sciences and Mathematics), Olga Voutsikaki (Municipality of Thessaloniki), Pascale Delzenne (Bayer), Petra Kostolaniova (CropLife Europe), Remziye Yilmaz (Hacettepe University), Romaan Raemaekers (Syngenta), Sasi Wilhelmi (BASF), Stefano Brizzi

(BASF), Tewodros Duressa (Bayer), Vaios Fytsilis (Maastricht University), Valerie Sert (Corteva Agriscience), Wolfram Reichenbecher (Federal Agency for Nature Conservation), Yukun Zhang (Syngenta).

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

2. Presentation of the guidelines for observers

The Chair presented the guidelines for observers for open plenary meetings.[1]

3. Adoption of agenda

The agenda was adopted without changes.

4. 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.

5. Report on written procedures since the 153rd GMO Plenary meeting

Since the 153rd Plenary meeting, four outputs have been adopted by written procedure:

5.1. The minutes of the 153rd Plenary meeting

The minutes of the 153rd Plenary meeting were adopted by written procedure and published on 12 October 2022.

5.2. 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 MON 87701 and products other than food and feed containing or consisting of it with the exception of cultivation, authorised under Regulation 1829/2003 (Commission Implementing Decision 2012/83/EU) submitted by Bayer CropScience LP (EFSA-GMO-RX-021)[4]

[1] https://www.efsa.europa.eu/sites/default/files/observersguidelines.pdf
[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] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00061

The draft opinion was presented for possible adoption at the 153rd Plenary meeting held on 28-29 September 2022.[5] It was agreed to adopt the opinion by written procedure after submission by the applicant of additional information (i.e. bioinformatic analysis update). The text of the scientific opinion was adopted by the GMO Panel via written procedure on 15 November 2022. The scientific opinion will be published on the EFSA website and in the EFSA Journal.

5.3. 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 MON 87701 × MON 89788 and products other than food and feed containing or consisting of it with the exception of cultivation, authorised under Regulation 1829/2003 (Commission Implementing Decision 2012/347/EU) submitted by Bayer CropScience LP (EFSA-GMO-RX-022)[6]

The draft opinion was presented for possible adoption at the 153rd Plenary meeting held on 28-29 September 2022.[7] It was agreed to adopt the opinion by written procedure after submission by the applicant of additional information (i.e. bioinformatic analysis update). The text of the scientific opinion was adopted by the GMO Panel via written procedure on 15 November 2022. The scientific opinion will be published on the EFSA website and in the EFSA Journal.

5.4. 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 40-3-2 and products other than food and feed containing or consisting of it with the exception of cultivation, authorized under Regulation 1829/2003 (Commission Decision (2012/82/EU) submitted by Bayer CropScience LP (EFSA-GMO-RX-023)[8]

The draft opinion was presented for possible adoption at the 153rd Plenary meeting held on 28-29 September 2022.[9] It was agreed to adopt the opinion by written procedure after submission by the applicant of additional information (i.e. bioinformatic analysis update). The text of the scientific opinion was adopted by the GMO Panel via written procedure on 15 November. The scientific opinion will be published on the EFSA website and in the EFSA Journal.

6. Scientific topics for discussion and possible adoption

6.1. Application for authorization of genetically modified maize GA21 × T25 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Syngenta (EFSA-GMO-DE-2016-137)[10]

Maize GA21 × T25 was produced by crossing to combine two single maize events expressing mEPSPS protein to confer tolerance to glyphosate-containing herbicides and the PAT protein to confer tolerance to glufosinate-ammonium-containing herbicides. The scope of the application EFSA-GMO-DE-2016-137 is for food and feed uses, import and processing and does not include cultivation in the EU.

[5] https://www.efsa.europa.eu/en/events/153rd-plenary-meeting-gmo-panel
[6] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00062
[7] https://www.efsa.europa.eu/en/events/153rd-plenary-meeting-gmo-panel
[8] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00077
[9] https://www.efsa.europa.eu/en/events/153rd-plenary-meeting-gmo-panel
[10] https://open.efsa.europa.eu/questions/EFSA-Q-2016-00775

The GMO Panel revised the draft opinion, and where appropriate, questions were raised and addressed throughout the different sections. The GMO Panel adopted the opinion, which will be published on the EFSA website and in the EFSA Journal.

6.2. Application for authorization of genetically modified maize MON 87419 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto Europe S.A./N.V. (EFSA-GMO-NL-2017-140)[11]

Maize MON 87419 was produced by *Agrobacterium*-mediated transformation and expresses DMO and PAT proteins conferring tolerance to dicamba- and glufosinate-containing- herbicides. The CP4 EPSPS protein was used as a selectable marker during the transformation process and was eliminated by crossing. The scope of the application EFSA-GMO-NL-2017-140 is for food and feed uses, import and processing and does not include cultivation within the EU.

The GMO Panel revised the draft opinion, and where appropriate, questions were raised and addressed throughout the different sections. The GMO Panel adopted the opinion, which will be published on the EFSA website and in the EFSA Journal.

6.3. Application for authorization of genetically modified maize Bt11 x MIR162 x MIR604 x MON89034 x 5307 x GA21 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Syngenta Crop Protection NV/SA (EFSA-GMO-DE-2018-149)[12]

Maize Bt11 x MIR162 x MIR604 x MON89034 x 5307 x GA21 was produced by crossing to combine six single maize events: expressing Cry1Ab, Cry1A.105, Cry2Ab2 and Vip3Aa20 proteins to confer resistance to certain lepidopteran pests, eCry3.1Ab and mCry3A proteins to confer resistance to certain coleopteran pests, mEPSPS protein to confer tolerance to glyphosate-containing herbicides, PAT protein to confer tolerance to glufosinate-ammonium-containing herbicides and PMI protein used as a selectable marker. The scope of the application EFSA-GMO-DE-2018-149 is for food and feed uses, import and processing and does not include cultivation within the EU.

Due to new information that was made available via the public consultation submitted in the frame of recently published opinions (see also item 7.2), the GMO Panel requested further clarifications from the applicant. Therefore, the scientific opinion can be proposed for discussion and not for possible adoption.

The GMO Panel revised the draft opinion, and where appropriate, questions were raised and addressed throughout the different sections. It was not possible to revise some of the sections due to the lack of the requested clarifications. The scientific opinion will be tabled for discussion in upcoming Plenaries.

6.4. Statement on animal dietary exposure assessment for GM feed[13]

EFSA carries out the risk assessment of genetically modified plants for food and feed uses under Regulation (EU) 503/2013. Exposure assessment - anticipated intake/extend of use shall be an essential element of the risk assessment of genetically modified feeds, as required by Regulation (EU) No 503/2013. Estimates of animal dietary exposure to newly expressed proteins should be determined to cover average consumption across all the different species, age, physiological and productive phases of farmed and companion animals, and identify and consider particular consumer groups with expected higher exposure. This statement is aimed at facilitating the reporting of information that applicants need to provide. Advice is provided on the selection of proper feed consumption and feed concentration data, and on the reporting of exposure's estimates. An overview of the different uncertainties that may be linked to the estimations is provided. This statement also explains how to

[11] https://open.efsa.europa.eu/questions/EFSA-Q-2017-00263
[12] https://open.efsa.europa.eu/questions/EFSA-Q-2018-00292
[13] https://open.efsa.europa.eu/questions/EFSA-Q-2022-00433

access an Excel calculator which should be used in future applications as basis to provide a more consistent presentation of estimates of expected animal dietary exposure.

The GMO Panel revised the draft statement, and where appropriate, questions were raised and addressed throughout the different sections. The GMO Panel adopted the statement, which will be published on the EFSA website and in the EFSA Journal.

7. New mandates

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

None

7.2. Upcoming mandates

- **Mandate on additional information on maize MIR162[14]**

On 28 November 2022, the European Commission mandated EFSA to consider whether, on the basis of the new information submitted via public consultation[15][16] of two recently published opinions, the conclusions for the adopted opinions[17] containing MIR162 remain valid. The timeline for this mandate is two months.

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

The Chair of the GMO Panel reported on discussions at the last Scientific Committee meeting and ongoing EFSA activities.[18]

The Panel members were also updated on the activities of the WG on Protocol Development[19] which is relevant for the Panel's work on generic mandates.

8.2. EFSA including its Working Groups/Task Forces

The Panel was updated on the establishment of the new WG that will carry out the EC mandate requesting EFSA to produce an opinion under Article 29 of Regulation (EC) No 178/2002 on new developments in biotechnology applied to microorganisms [20] (GMM-NGT WG). The first meeting of the GMM-NGT WG is planned at the end of 2022.

8.3. European Commission

[14] https://open.efsa.europa.eu/questions/EFSA-Q-2022-00853
[15] https://food.ec.europa.eu/system/files/2022-09/gmo_pub-cons_comments_2022-7451.pdf
[16] https://food.ec.europa.eu/system/files/2022-11/gmo_pub-cons_comments_mir162.pdf
[17] Maize Bt11 × MIR162 × MIR604 × GA21 (EFSA-GMO-DE-2009-66), Bt11 × MIR162 × 1507 × GA21 (EFSA-GMO-DE-2010-86), Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 (EFSA-GMO-DE-2011-103), MON 87427 × MON 89034 × MIR162 × MON 87411 (EFSA-GMO-2017-144), MON 87427 × MON 89034 × MIR162 × NK603 (EFSA-GMO-NL-2016-131), MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 (EFSA-GMO-NL-134) and 1507 × MIR162 × MON810 × NK603 (EFSA-GMO-NL-2015-127)
[18] https://www.efsa.europa.eu/en/events/111th-plenary-meeting-scientific-committee
[19] https://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-protocol-development.pdf
[20] https://open.efsa.europa.eu/questions/EFSA-Q-2022-00508

The representatives of the 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.

9. Other scientific topics for information and/or discussion

9.1. Upcoming EFSA stakeholder event on NGTs[21]

The Unit informed that the preparation of the stakeholder event on 'The safety of plants derived from New Genomic Techniques: looking into future risk assessment challenges' is ongoing. The event will be held on the 12 December 2022 in remote mode and the registration are open until 9 December.

10. Any other business

None

11. Questions from and answers to Observers

Observers were invited to submit questions to the GMO Panel at the time of registration. EFSA received the following questions ahead of the meeting:

NUMBER	QUESTION	ANSWER
1	It is a generally accepted risk assessment principle that the need for an exposure assessment is triggered if a hazard is identified. Therefore, it is not implicit in Implementing Regulation 503/2013 that a derogation of the requirement cannot be applied in the absence of a hazard. Could you confirm that if a hazard is not identified, the exposure assessment is not scientifically necessary?	Besides the general principles, it is noted that the GMO Panel performs the risk assessment of GM plants for food and feed uses under Regulation (EU) No 503/2013, which provides that "all the requirements of Part II shall be provided in the application except where such requirements are not justified by the scope of the application (for example, where the application is limited to food or feed produced from GMOs)". This includes also information on exposure assessment - anticipated intake or extent of use. Derogation is a subject of case-by-case evaluation and should be looked in the context of applications. The aim of the GMO Panel statement on ADE is targeted to provide advice to harmonise the reporting under Regulation (EU) No 503/2013.
	In addition, use of the term dietary exposure assessment in the draft statement for product for which no hazard has been identified could be misinterpreted as suggesting a hazard for animals. Can you explain the added value of	In the GMO Panel statement on ADE, the term dietary exposure is used instead of dietary intake since the focus of the assessment of newly expressed proteins (e.g. NEPs conferring resistance to

[21] https://www.efsa.europa.eu/en/events/stakeholder-event-safety-plants-derived-new-genomic-techniques-looking-future-risk

	calculating the worse-case values for all species?	insects or herbicides) is on their safety, rather than on their nutritional relevance. The selected animal species proposed in the GMO Panel statement on ADE aim to cover the differences across animals, in term of class, nutritional behaviour and requirements related to specificities of the digestive tract.
2	Would it be more informative in application opinions to explain in detail how such calculations are worse case and that proteins will be providing necessary amino acids to human and animals? Would it be possible to not use 'dietary exposure assessment' which can be interpreted as suggesting a hazard. Would it not be better to refer to NEP intake evaluation?	The conservativeness of the approach is described in several sections of the GMO Panel statement on ADE. The GMO Panel will consider the recommendation to further clarify this aspect in the scientific opinions. It is not the purpose of the GMO Panel statement on ADE to make considerations on the nutritional aspects of the newly expressed proteins. In the GMO Panel statement on ADE, the term dietary exposure is used instead of dietary intake since the focus of the assessment of newly expressed proteins (e.g. NEPs conferring resistance to insects or herbicides) is on their safety, rather than on their nutritional relevance.
3	I understand that GMOs are meant to improve the worlds production of quality food to mitigate the issue of insufficiency of food. however, there are a lot of myths and misconceptions surrounding the products. what is EFSA doing to ensure that the consumer is well informed about GMOs to enable them to make informed choices? thank you	EFSA was set up in January 2002 as an independent source of scientific advice and communication on risks associated with the food chain. EFSA's remit in the risk assessment of GMOs includes GM plants, GM microorganisms and GM animals, and involves the assessment of their safety for humans, animals and the environment. EFSA's responsibilities also include communicating its scientific advice to its principal partners, stakeholders and the public at large in a timely, clear, accurate and meaningful way. All EFSA output are accessible on the EFSA website and on the EFSA Journal. In addition, thematic webpages are kept updated on the EFSA website including the ones on GMOs and on the new advances in biotechnologies. EFSA also offers webinars and events to disseminate the output of scientific activities (e.g. the upcoming Stakeholder Event on 'The safety of plants derived from New Genomic Techniques: looking into future risk assessment challenges' see item 9 of the current meeting). EFSA also periodically organises scientific

		conferences has recently done in June 2022. Finally, EFSA staff and Experts also attend scientific events and dissemination meetings to present their work.

In addition to the questions referred to above, observers could also pose questions during the meeting. Questions received (exact quote from web-streamers) and replies given by Panel member or GMO Unit staff are reported in the table below.

AGENDA ITEM	QUESTION	ANSWER
6.3	In case of this particular stack, expressing herbicide-tolerant and insect-resistant traits, we do not see how missing data on ear count can inform the food/feed risk assessment and therefore we ask the EFSA GMO Panel to explain for which hypothesi(e)s (and corresponding pathway(s) to harm) they consider the additional requested information relevant.	The EFSA GMO Panel in its guidance on the agronomic and phenotypic characterisation of genetically modified plants (EFSA GMO Panel, 2015) identified a minimum set of endpoints that allows to detect and measure agronomic and phenotypic differences between the GM plant and its conventional counterpart. Ear count (or fruit count in other crops) is one of the required mandatory endpoints. As reported in the guidance, *ear count is an important yield component, providing an indication of plant fertility*. Changes in plant fertility can impact on the invasiveness and persistence of the event/stack under assessment. The EFSA GMO Panel acknowledges that ear count / fruit count is usually characterised by low variability in maize and in two occasions discussed with applicants this specific issue (ad-hoc meeting with industry representatives hold in 2019 and 2022). The applicant was informed on how to compensate the eventual lack of this endpoint in maize; however, it was reminded that it is always recommended to provide this endpoint to avoid any possible delay on the assessment of the GMO Panel. Indeed, a possible unintended effect observed on plant fertility might require to investigate variability in ear count and the lack of this data might represent a gap.
6.4	While the IR 503/2013 indicates that exposure assessment is an essential part of risk assessment, with which we agree, there is no indication in the IR 503/2013 (nor the	Concentration data of the NEPs in feed materials obtained from the GMP stacked-event are the most appropriate to estimate expected ADE. The dietary

	EFSA guidelines of 2011 that formed the basis of the IR 503/2013) – or it was not the intention that the IR 503/2013 would be read that way - that an ADE should be required for every application. E.g. in case of a stack where it is shown that there is no change in the expression levels of the traits, we do not see the relevance of having such an ADE. This on a side note to share our point of view.	exposure to NEPs in a GMP stacked-event may differ from the exposure in the context of the respective GMP single-events previously assessed, as a consequence of potential differences in either consumption data (e.g. new feed materials enter the market) or concentration data (e.g. expression levels in the stack are the combined/additional result of two or more events of the GMP stack). Therefore the GMO Panel recommends for the estimation of expected ADE to NEPs in GMP stacked-event the use of concentration data determined in feed materials obtained from the GMP stacked-event itself.
6.4	Dear EFSA, linked to response to my question, do I understand it correctly that proteins have no nutritional value?	In reply to your question, it was explained that in the case of newly expressed proteins (e.g. NEPs conferring resistance to insects or herbicides) the interest is on their safety, rather than on their nutritional relevance. This does not mean that proteins have no nutritional value in general.
General	If I understood correctly all activity is focusing on GMO plants. Will gene edited animals also be addressed?	EFSA received applications for authorisation of GM plants and GM microorganisms. So far, no applications for GM animals were submitted. EFSA published a series of guidance documents on GM animals and more recently a scientific opinion on the adequacy of the EFSA guidelines for the assessment of genetically modified insects containing engineered gene drives. Currently at EFSA there are no activities on gene edited animals, but EFSA is contacting the European Commission in the context of the broad mandate on Synthetic Biology.

12. Adoption of the minutes and next meeting

The minutes of the current meeting will be adopted by written procedure and will be published at: https://www.efsa.europa.eu/en/events/154th-plenary-meeting-gmo-panel-open-observers

The 155th GMO Plenary meeting will be held on 25-26 January 2023 online.