Scientific Panel on GMO

Minutes of the 124th Plenary meeting

Held on 20 – 21 June 2018, Parma (Italy)

(Agreed on 21 June 2018)

Participants

- Panel Members:

  Nicholas Birch, Mikolaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan, Hanspeter Naegeli, Elsa Nielsen, Fabien Nogué, Christophe Robaglia, Nils Rostoks[1], Jeremy Sweet, Francesco Visioli and Jean-Michel Wal

- Hearing Experts[2]:

  None

- European Commission representatives:

  Béatrice Marquez-Garrido, Hans Moons and Alexandre Huchelmann (DG SANTE)

- EFSA:

  GMO Unit: Fernando Álvarez, Michele Ardizzone, Herman Broll, Giacomo De Sanctis, Yann Devos, Antonio Fernández Dumont, Silvia Federici, Andrea Gennaro, José Ángel Gomez Ruiz, Anna Lanzoni, Sylvie Mestdagh, Franco Maria Neri, Claudia Paoletti, Nikoletta Papadopoulou, Konstantinos Paraskevopoulos, Matthew Ramon and Elisabeth Waigmann

  Other EFSA Units/Directorates: none

- Observers (in application of the guidelines for observers[3]): None

- Others: None

[1] Apologies were received for day 2.

[2] 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.

[3] http://www.efsa.europa.eu/en/stakeholders/observers.html

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Josep Casacuberta, Adinda De Schrijver and Christoph Tebbe.

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[4] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interest[5], EFSA screened the Annual Declarations of Interest (ADoIs) and the Specific Declarations of Interest (SDoIs) filled in by the experts invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting. For further details on the outcome of the screening of the ADoI and SDoI, please refer to Annex I. Philippe Guerche did not participate to the discussion on agenda item 5.2 due to a specific conflict of interest.

Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Report on written adoption procedure since 123rd Plenary meeting

The minutes of the 123rd plenary meeting held on 30-31 May 2018 were adopted by a majority of the experts on 18 June 2018 and were published on 19 June 2018 on the EFSA website.

In addition, the Technical Note on the quality of DNA sequencing was adopted by written procedure on 14 June 2018. The Note will be published on the EFSA website and on the EFSA journal in the coming weeks.

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

5.1. Assessment of genetically modified maize 1507 x NK603 for its authorisation renewal for food and feed

[4] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdfReq

[5] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-008) (EFSA-Q-2017-00029)

Maize 1507 x NK603 was developed to produce Cry1F, an insecticidal protein conferring resistance against certain lepidopteran pests, as well as PAT and CP4 EPSPS proteins to confer tolerance to glyphosate-based and glufosinate ammonium-based herbicides. Application EFSA-GMO-RX-008 was submitted by Pioneer Overseas Corporation and Dow AgroSciences Europe for an authorisation renewal for import and processing for food and feed uses under Regulation (EC) No 1829/2003.

A member from the GMO Unit explained that draft text of the scientific opinion was discussed at length by each standing Working Group.

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.

5.2. Assessment of genetically modified soybean MON 87751 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-121) (EFSA-Q-2014-00719)

Soybean MON87751 was developed to produce two insecticidal proteins, Cry2Ab2 and Cry1A.105, which confer resistance against certain lepidopteran pests. Application EFSA-GMO-NL-2014-121 was submitted by Monsanto Europe S.A./N.V. for the import and processing for food and feed uses of soybean MON87751 in the European Union.

Application EFSA-GMO-NL-2014-121 is the first GMO dossier submitted to EFSA after the entry into force of Regulation (EU) No 503/2013[6]. In this respect application EFSA-GMO-NL-2014-121 should be fully compliant with the legal requirements laid down in Regulation (EU) No 503/2013 (e.g. literature review, mandatory 90-day animal feeding study, estimated intake and dietary exposure assessment).

The GMO Panel was reminded that the text of the scientific opinion was already discussed at its October 2017 and March 2018 plenary meetings. In March 2018 the GMO Panel could not conclude its risk assessment since clarifications on the 28-day studies spontaneously provided by the applicant were still awaited. Following receipt of the additional information, the standing Working Group on Food/Feed assessment of the GMO Panel finalized its toxicological assessment.

In this meeting, the GMO Panel scrutinized and revised the draft text, where appropriate. The GMO Panel subsequently adopted the draft

[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, L157/1-48.

opinion, which will be published on the EFSA website and on the EFSA Journal.

5.3. Assessment of genetically modified cotton GHB614 x T304-40 x GHB119 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-122) (EFSA-Q-2014-00721)

Cotton GHB614 x T304-40 x GHB119 was developed to produce insecticidal proteins, Cry1Ab and the Cry2Ae, which confer resistance against certain lepidopteran pests, as well as 2mEPSPS and PAT/bar proteins to confer tolerance to glyphosate- and glufosinate ammonium-based herbicides.

A member of the EFSA GMO Unit reminded that application EFSA-GMO-NL-2014-122 is the first dossier on a stack event submitted to EFSA under Regulation (EU) No 503/2013[6]. Application EFSA-GMO-NL-2014-122 was submitted by Bayer CropScience N.V. for the import and processing for food and feed uses of cotton GHB614 x T304-40 x GHB119 in the European Union.

A member from each standing Working Group reported the main findings of their risk assessment. 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

On 31 May 2018, EFSA received the following new application from Dow:

- EFSA-GMO-NL-2018-151 on maize MON 89034 x1507 x MIR162 x NK603 x DAS-40278-9 under Regulation (EC) No 1829/2003

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

None

6.3. Other Requests and Mandates

On 6 June 2018, EC mandated EFSA for an opinion on GMOs engineered with gene drives and their implications for risk assessment methodologies.

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

The Chair of the GMO Panel reported on ongoing activities, new guidance documents and progress made by the Scientific Committee (minutes of the 89th meeting of the Scientific Committee).

A member of the GMO Unit reported on the Scientific Colloquium on "Omics in risk assessment: state-of-the-art and next steps" that took place on 24-25 April 2018. The opportunities for integrating datasets produced via specific OMICS tools within the remit of EFSA's risk assessment approaches were considered and discussed at length. The report of this Scientific Colloquium is expected to be published in autumn 2018.

7.2. EFSA including its Working Groups /Task Forces

None

7.3. European Commission

The representative of the European Commission informed the GMO Panel about the cancelation of the PAFF meeting of 10 July 2018. Next PAFF meeting will take place on 11 September 2018.

8. Other scientific topics for information and/or discussion

8.1. Explanatory technical note on newly expressed proteins levels data

A member of the EFSA GMO Unit presented the draft explanatory note on the determination of newly expressed proteins (NEPs) levels in the context of GMO applications for market authorisation in the European Union (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 explanatory note on the determination of NEPs levels in the context of GMO applications for EU market authorisation will be published on the EFSA website and on the EFSA Journal.

9. Any other business

None

10. Adoption of the minutes of the current meeting

The minutes of the current meeting were adopted on 21 June 2018.

Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

CONFLICT OF INTEREST: In the SDoI filled for the present meeting, Philippe Guerche declared an interest for Item 5.2 in relation to previously declared annual declaration of interest (ADOI): Mr Guerche commented on dossiers submitted to EFSA including application for authorisation of genetically modified soybean MON 87751 for food and feed uses, import and processing (EFSA-GMO-NL-2014-121) submitted to EFSA under Regulation (EC) No 1829/2003 by Monsanto, in his capacity of member of the French High Council for Biotechnology (FSO), which advises the French government on GMOs. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[7] and the Decision of the Executive Director on Declarations of Interest[8], and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of the item 5.2.

[7] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[8] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf