GENETICALLY MODIFIED ORGANISMS UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 140th MEETING

Held on 9 November 2020, TELE/WEB

(Agreed on 12 November 2020)

Participants

- Panel Members:

  Jean-Louis Bresson, Tamas Dalmay, Ian Dewhurst, 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

- Hearing expert[1]: - not applicable

- European Commission and/or Member States representatives:

  Olga Orlova and Juliette-Marie Margueritte (DG SANTE)

- EFSA:

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

  AMU Unit: Laura Martino

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Michelle Epstein.

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 139th GMO Plenary meeting

The minutes of the 139th Plenary meeting were adopted by written procedure and published on 06 November 2020.

5. Scientific topic(s) for discussion

5.1 Draft framework for protocol development for EFSA's scientific assessments

The Chair of the GMO Panel, Hanspeter Naegeli, briefly introduced the new draft framework setting recommendations to EFSA scientific Panels for the protocol development for non-applications scientific assessments. A protocol is to be developed by scientific Panels when they receive so called generic mandates received from European Commission, European Parliament or Member States, etc.

A scientific officer of the Assessment and Methodology Unit (AMU Unit), Laura Martino, provided the Panel with background info about the draft framework, the concept and the details of the recommendations. EFSA called for a harmonised approach in addressing generic mandates for sake of methodological rigour and transparency. Moreover the protocol development is in line with the legislator's intention of the new Transparency law entering into force in March 2021.

The draft framework was prepared by a Working Group[4] made of members from different Panels and scientific officers across scientific Units. The draft framework developed by the aforementioned WG is up for a pilot phase aiming testing the recommendations and collecting feedback on their implementation (e.g. omissions, unclarities). The pilot will be concluded by May 2021. Laura reiterated that the scope of the pilot is to test the recommendations in all generic mandates/assessments whereas testing the protocol approach is out of scope as it was already done under a previous EFSA programme.

The draft framework covers in a step-wise approach

(1) the protocol planning including the problem formulation (i.e. breaking down the mandate into assessment questions), the definition of evidence needs and methods, and

(2) the extended planning for risk assessment including the retrieval/collection of evidence (e.g. from scientific literature, through experts knowledge elicitation), the evidence integration and interpretation of results.

The document is structured in two main parts: rationale for a protocol followed by steps & recommendations. Laura drew the attention of the Panel to both Appendices i.e. Appendix A as a list

[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://ess.efsa.europa.eu/doi/doiweb/wg/685630

of main EFSA questions and Appendix B providing an overview of methods for evidence synthesis and integration.

Following the pilot, the final framework with a set of recommendations (but recommendations on problem formulation might be delayed for administrative reasons) will be finalised and published.

The GMO Panel Chair opened the floor to discussion and questions. Laura Martino clarified that the protocol development is embedded into the revised process for generic mandates as designed for the entry into force of the new Transparency law in March 2021. The scientific planning will include a so called frontloading exercise aiming at consulting and negotiating the terms of reference of a mandate with the requestor. During this discussion, the requestor and EFSA discuss the timeline and address the scientific value (e.g. methodological rigor, degree of engagement). A new collaborative tool is currently set up to facilitate the upfront discussion between the requestor(s) (e.g. European Commission) and EFSA.

5.2. Discussion for implementation on GMO mandate

The scientific officer of the GMO Unit in charge, Tommaso Raffaello, introduced the mandate on *in vitro* random mutagenesis lately received from the EC. The mandate was triggered by the ruling of the French Conseil d'Etat as regards the interpretation of Annex I.B of Directive 2001/18/EC on the deliberate release of GMOs (including a list of techniques/methods of genetic modification yielding organisms to be excluded from the Directive, including mutagenesis). The EC asked EFSA to reflect on the differences between *in vitro* and *in vivo* random mutagenesis and to conclude whether or not *in vitro* and *in vivo* random mutagenesis should be seen as different mutagenesis techniques or rather as a continuum. A final output is expected by September 2021.

The Working Group of the GMO Panel on Molecular Characterisation (hereafter referred to as 'MC WG) is tasked to address this mandate and the protocol development. At the kick off meeting on 13 November, the MC WG will discuss and consider breaking down the Terms of reference of the mandate in (sub-)questions. Being key players in the protocol development, representatives of the European Commission as requestor are invited to WG meetings for joint discussion and decision on the scope of the mandate at stake (e.g. plants, animals).

The MC WG may consider the need for evidence e.g. through a literature review. Would such a review be outsourced, Laura Martino advised to provide as many guidelines possible to the outsourcer on how the literature review should be conducted (e.g. search string, databases). The GMO Panel also sought for feedback from more experienced Panels and Units on the types (qualitative vs quantitative) of necessary evidence.

6. Adoption of the minutes and next meeting

The minutes of the current meeting were adopted by written procedure and will be published on https://www.efsa.europa.eu/en/events/event/140th-plenary-meeting-gmo-panel

The 141st GMO Plenary meeting will be held on 25-26 November online.