Scientific Panel on GMO

Minutes of the 115th Plenary meeting

Held on 17 – 18 May, 2017, Parma (Italy)

(Agreed on 18 May 2017)

Participants

- Panel Members

  Nicholas Birch, Adinda De Schrijver, Mikolaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan, Hanspeter Naegeli, Elsa Nielsen, Fabien Nogué, Christophe Robaglia, Nils Rostoks, Jeremy Sweet, Christoph Tebbe, Francesco Visioli and Jean-Michel Wal.

- Hearing Experts[1]: Frits Koning for item 5.1, Salvatore Arpaia for item 8.2.
- European Commission representatives: Lisa Haller and Beatrice Marquez-Garrido.
- EFSA:

GMO Unit: Fernando Álvarez, Herman Broll, Giacomo De Sanctis, Yann Devos, Andrea Gennaro, Mildred Hauck, Anna Lanzoni, Sylvie Mestdagh, Irina Olaru, Franco Neri, Nikoletta Papadopoulou, Konstantinos Paraskevopoulos, Matthew Ramon, José Ángel Ruiz and Elisabeth Waigmann.
Other EFSA Units/Directorates: Jaime Aguilera (Feed Unit/REPRO) for item 5.5.

- Observers (in application of the guidelines for observers[2]): none.
- Others: none.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Josep Casacuberta.

2. Adoption of agenda

The agenda was adopted with two changes: the addition of points 5.5 and 7.1.1.

3. Declarations of Interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[3] and the Decision of the Executive Director on Declarations of Interest[4], EFSA

[1] 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.

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

[3] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

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

screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the experts invited for 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. Report on written adoption procedure since 114th Plenary meeting

There were no outputs submitted for written adoption since the previous GMO Panel plenary meeting.

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

5.1. Self-task mandate of the EFSA GMO Panel to establish a new working group activity to develop supplementary guidelines for the allergenicity assessment of GM plants to incorporate new developments (EFSA-Q-2014-00547)

The guidance on allergenicity assessment of GM plants had been discussed in the July 2016 GMO Panel plenary meeting.[5] Since then, it had gone through public consultation and had been updated in order to address the received comments. The GMO Panel discussed and revised the draft text of the guidance document and its annexes, as needed.

The GMO Panel adopted this scientific opinion, which will be published on the EFSA website at EFSA Journal.

5.2. Application for renewal of the authorisation of food and feed containing, consisting and produced from genetically modified maize DAS-59122-7 and products other food and feed containing or consisting of it with the exception of cultivation, authorized under Regulation (EC) No 1829/2003 from Dow AgroSciences (Commission Decision 2007/702/EC) (EFSA-GMO-RX-003) (EFSA-Q-2016-00526)

This was the first time the GMO Panel discussed the draft opinion.

Maize DAS-59122-7 produces Cry34Ab1, Cry Ab1 and PAT proteins, conferring resistance to specific lepidopteran pests and tolerance to glufosinate ammonium. This single event had been assessed by the GMO Panel in the context of application EFSA-GMO-NL-2005-12[6] and authorised by Commission Decision 2007/702/EC; application EFSA-GMO-RX-003 was submitted to EFSA for the renewal of the authorisation.

The GMO Panel adopted this scientific opinion, which will be published on the EFSA website at EFSA Journal.

5.3. Application for authorisation of genetically modified maize MON 87427 x MON 89034 x NK603 for food and

[5] http://www.efsa.europa.eu/en/events/event/160713
[6] http://www.efsa.europa.eu/en/efsajournal/pub/470

feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-BE-2013-117) (EFSA-Q-2013-00765)

The GMO Panel had discussed this application in the previous plenary meeting.[7] In this meeting, the GMO Panel discussed and finalised the section on sub-combinations of the draft opinion. Further discussion may be needed, pending the arrival of additional information.

5.4. Application for authorisation of genetically modified maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-BE-2013-118) (EFSA-Q- 2013-00926)

This was the first time the GMO Panel discussed the draft opinion.

Maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 was obtained by conventional crossing of maize lines MON 87427, MON 89034, 1507, and MON 88017. Maize MON 87427 produces CP4EPSPS, which confers tolerance to glyphosate. Maize MON 89034 produces Cry1A.105 and Cry2Ab2, which confer resistance to specific lepidopteran pests. Maize 1507 produces Cry1F and PAT, conferring resistance to specific lepidopteran pests and tolerance to glufosinate ammonium. Maize MON 88017 produces CP$ EPSPS and Cry3Bb1, conferring resistance to specific lepidopteran pests and tolerance to glyphosate. Maize 59122 produces Cry34Ab1, Cry Ab1 and PAT, conferring resistance to specific lepidopteran pests and tolerance to glufosinate ammonium. The single events are maintained in the maize stack MON 87427 x MON 89034 x 1507 x MON 88017 x 59122.

The GMO Panel revised the draft opinion, focusing on the molecular characterisation and comparative assessment of the five-event stack. Further discussion may be needed, pending the arrival of additional information.

5.5. Guidance on the characterisation of microorganisms used as feed additives or as production organisms

Since the previous GMO Panel plenary meeting, section 4.2 had been updated, therefore the GMO Panel was asked to review the change and to endorse the updated text.

The GMO Panel endorsed the updated section of the guidance. This document will be published for public consultation on the EFSA website.

6. New Mandates

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

Three new applications were presented:

- EFSA-GMO-DE-2017-141
- EFSA-GMO-DE-2017-142
- EFSA-GMO-NL-2017-143

[7] http://www.efsa.europa.eu/sites/default/files/event/170405-m.pdf

Further information on these applications can be found at EFSA Register of Questions.

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

None.

6.3. Other Requests and Mandates

One new mandate was presented:

- Mandate to assess additional information related to maize 3272 (EFSA-GMO-UK-2006-34)

7. Feedback from the Scientific Committee/Scientific Panels, EFSA and the European Commission

7.1. Scientific Committee and/or Scientific Panel(s) including their Working Groups

7.1.1. Feedback from ERA WG on PMEM reports

In the context of the assessment of several applications for the renewal authorisation of GM plants for food and feed uses, import and processing, the environmental risk assessment (ERA) working group has been analysing the content of the annual post market environmental monitoring (PMEM) reports as well as the relevance of their underlying monitoring methodology.

The PMEM plans proposed by applicants consist mainly of general surveillance of imported GM plant material. This general surveillance is coordinated by EuropaBio and implemented by selected operators (federations involved in import and processing). In addition, applicants review relevant scientific publications retrieved from literature searches on an annual basis.

Although the final adoption of the PMEM plans fall outside the remit of EFSA, the GMO Panel considers that further discussion with applicants and risk managers is needed on the practical implementation of the PMEM for GM plants for import and processing (e.g. actual data gathered on exposure and/or adverse effects as implemented in existing monitoring systems).

7.2. EFSA including its Working Groups /Task Forces

None.

7.3. European Commission

The representatives of the European Commission informed the Panel on their on-going activities, approval procedures for applications for which the GMO Panel had issued a scientific opinion, and upcoming mandates.

8. Other scientific topics for information and/or discussion

8.1. Case study to test implementation of the Uncertainty Analysis guidance

A Panel member presented a case study for the implementation of the EFSA Scientific Committee's uncertainty analysis guidance document.

8.2. AMIGA presentation

Salvatore Arpaia presented the outcome of the AMIGA project.[8] The GMO Panel discussed the findings of the project.

8.3. Risk assessment of sub-combinations

The GMO Panel discussed and adopted the document illustrating the general strategy for the risk assessment of sub-combinations in segregating stacks, described in Annex 1 of these meeting minutes.

9. Any other business

9.1. GMO Network meeting

A member of the GMO Unit presented the draft agenda of the EFSA Scientific Network for Risk Assessment of GMOs meeting, taking place on 23-24 May 2017.

10. Adoption of the minutes of the current meeting

The minutes of the current meeting were adopted at the end of the meeting.

[8] http://www.amigaproject.eu/

Annex 1
GMO Panel approach for the risk assessment of sub-combinations as required by Implementing Regulation (EU) No 503/2013

Background

According to Commission Implementing Regulation (EU) No 503/2013 (hereafter referred to as "IR 503/2013"), the scope (food and feed uses, import and processing) of the risk assessment of segregating genetically modified (GM) crops containing multiple events introduced by conventional crossing of GM plants 'the stack' must include also the assessment of related lower stacks, i.e. stacks containing respectively, all possible combinations of the events present in the stack. Hereafter, we only refer to applications for food and feed, import and processing and dossiers with scope 'cultivation' are not covered by the present document.

The term 'sub-combination' is used in IR 503/2013 to refer to lower stacks containing up to N-1 combinations[9] s of the events present in the stack and should be assessed 'independently of their origin', which can be obtained in two ways:

- By segregation in the progeny of the stack (harvested grains/seeds)
- By conventional crossing, through breeding programs targeted to combine up to N-1 of the events present in the stack into varieties that can be bred, produced and marketed independently of the stack.

The EFSA GMO Panel risk assessment strategy for stacks requires the preceding individual risk assessments of all the single events combined in the stack, as well as the data package for the stack, which includes data on the harvested grains/seeds - e.g. the F_2 segregating progeny (the respective data requirements are described in EFSA GD, 2011 and IR 503/2013). More broadly, according to IR 503/2013, for sub-combinations obtained by conventional crossing, through targeted breeding programs and included in the scope, *applicants should either provide a scientific rationale justifying that there is no need to provide experimental data or, in the absence of such scientific rationale, provide the experimental data*. It must be pointed out that such sub-combinations may have not been produced at the moment of submission of the stack application and, consequently, it may not be possible to obtain specific data packages.

Goal of this document

Define a GMO Panel strategy for the risk assessment of sub-combinations of maize and rapeseed independently of their origin, i.e. obtained by segregation or by conventional crossing, as required in IR 503/2013. To enhance full transparency of the risk assessment process, possible risk assessment scenarios are considered here.

[9] N indicates the number of events stacked in the submitted application.

Risk Assessment Strategy

Sub-combinations obtained by segregation in the progeny of the stack (e.g. F_2 generation in harvested grains/seeds)

Sub-combinations occurring as segregating progeny are present in the stack F_2 grain/seed mixture, which contains each sub-combination in a specific proportion that can be considered representative of the food/feed grain material harvested, which is then imported into Europe. Such material is not intended to be further propagated and its assessment is completed analyzing the composition of the F_2 grain/seed mixture, which is an integral part of the assessment of the stack. Therefore, the assessment of sub-combinations occurring by segregation needs no further consideration.

Sub-combinations produced by conventional crossing, through targeted breeding programs

Sub-combinations obtained by conventional crossing, through plant breeding programs targeted to combine up to N-1 of the events present in the stack, are stacks in themselves which can be bred, produced and marketed independently of the stack at any time after its authorization. The strategy to assess these sub-combinations needs further consideration. In general, the EFSA GMO Panel frames the strategy for their assessment in the well-established GM plant risk assessment approach, applied to both singles and stacks, in which the molecular characterization and the comparative assessment - aiming at identifying differences between the GM plant and its conventional counterpart taking into account natural variation - are the starting pillars (Codex 2009; EFSA GMO Panel GD (2011); IR 503/2013). Such differences can be classified as:

- Intended: effects directly linked to the objective(s) of the genetic modification(s);
- Unintended: effects not directly linked to the objective(s) of the genetic modification(s). On the basis of current knowledge of the introduced trait(s), these can be either expected or unexpected.

Two are the critical challenges when assessing sub-combinations produced by conventional crossing through targeted breeding programs: first, since these sub-combinations can be bred, produced and marketed independently of the stack as grain and/or forage materials, they would be used *de facto* as a F_1 generation and as such must be considered when risk assessed. Second, since these sub-combinations may not even exist at the moment of submission of the stack application, it may not be possible to obtain specific data packages and to experimentally identify intended and unintended differences. On the other hand, it is also possible that some of these sub-combinations have been the object of past applications and assessed by the EFSA GMO Panel.

The EFSA GMO Panel considers that the assessment of sub-combinations produced by conventional crossing through targeted breeding programs can be performed on the basis of:

a) the outcome of risk assessment of the relevant single events;
b) the outcome of risk assessment of the stack;
c) the outcome of risk assessment of relevant specific sub-combinations (if available)
d) specific data/information that may be required on a case-by-case basis, as described below.

The opinion will report the assumptions made to complete the assessment of sub-combinations, and possible remaining uncertainties as well as, if appropriate, strategies to reduce such uncertainties.

Assessment of intended and expected unintended effect(s) linked to the genetic modification

When the risk assessment of the single events and/or that of the stack itself have identified effects linked to any event(s), the risk associated to particular combinations of these events can be anticipated when assessing sub-combinations. Two scenarios are identified:

a. An effect linked to specific sub-combinations is expected on the basis of the outcome of the assessment of the singles and/or that of the stack.
   - If the effect identified is of safety relevance for the assessment of the sub-combinations, during the risk assessment of the stack, supporting data/information on the respective sub-combination(s) is requested. If the requested supporting data/information cannot be provided, the opinion is inconclusive for those specific sub-combinations.
   - If the effect identified has no safety relevance for the assessment of the sub-combinations, no supporting data/information is requested and the assessment will be performed on the basis of the available information.

b. No effect linked to specific sub-combinations is expected on the basis of the outcome of risk assessment of the singles and/or that of the stack. There is no trigger to request additional data during the risk assessment of the stack and the assessment will be performed on the basis of the available information.

Unexpected unintended effect(s) potentially linked to the genetic modification

a. If an unexpected unintended effect is identified for the stack and/or any of the single events, it is assessed as an expected unintended effect, and its associated risk in specific sub-combinations is considered as described above (in a).
b. If no unexpected unintended effect is identified, the assessment will be performed on the basis of the available information.