Scientific Panel on GMO

Minutes of the 110th Plenary meeting of the Scientific Panel on GMO

26-27 October 2016, Brussels

(Agreed on 30 November 2016)

Participants

- **Panel members**:

Nicholas Birch, Josep Casacuberta, Adinda De Schrijver, Mikolaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan, Hanspeter Naegeli, Elsa Nielsen, Christophe Robaglia, Nils Rostoks, Jeremy Sweet, Christoph Tebbe, Francesco Visioli[1] and Jean-Michel Wal.

- **EFSA:**

GMO Unit: Fernando Álvarez, Herman Broll, Yann Devos[1], Antonio Fernández Dumont[1], Niccolò Franceschi[1], Andrea Gennaro, Anna Lanzoni[1], Franco Neri[1], Claudia Paoletti, Nikoletta Papadopoulou[1], Konstantinos Paraskevopoulos, Matthew Ramon, Regina Selb[1], Elisabeth Waigmann.

Other EFSA Units/Directorates:

REPRO department, APDESK Unit: Pagidas Alexandros.

Communication Department, EXREL Unit: Flavio Fergnani.

European Commission observers: Takis Daskaleros, Maria Mirazchiyska, Anastasia Pagida and Sirkku Heinimaa (DG SANTE).

- **Observers (in application of the guidelines for observers)**: See annex I.
- **Others:** none.

1 Welcome and apologies for absence

The Chair of the EFSA GMO Panel welcomed the participants. Apologies were received from Francesco Visioli for 26 October, from Adinda De Schrijver and Jeremy Sweet for 27 October, and from Fabien Nogue for 26 and 27 October.

2 Brief introduction of Panel members and Observers

The Chair welcomed the participants and invited them to introduce themselves.

[1] Attended via tele-conference.

3 Adoption of agenda

The agenda was adopted without changes.

4 Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[2] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[3], EFSA screened the Annual Declarations of Interest (ADoIs) and the Specific Declarations of Interest (SDoIs) filled in by the experts invited to the present meeting. For further details on the outcome of the screening of the ADoI and SDoI, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

5 Presentation of the Guidelines for Observers

The Head of the GMO Unit presented the EFSA Guidelines for Observers attending open plenary meetings.

6 Agreement of the minutes of the 109th Plenary meeting held on 21-22 September 2016, Parma

The minutes of the 109th Plenary meeting held on 21-22 September 2016 were adopted and will be published on the EFSA website at: Event: 109th plenary meeting of GMO Panel.

7 Scientific outputs submitted for discussion and/or possible adoption

7.1 Application for authorisation of genetically modified maize DAS-40278-9 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Dow AgroSciences (EFSA-GMO-NL-2010-89) (EFSA-Q-2010-01326)

Maize DAS-40278-9 was developed by direct Whiskers-mediated transformation to express the aryloxyalkanoate dioxygenase-1 (AAD-1) protein, conferring tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP) herbicides. The molecular characterisation of maize DAS-40278-9 did not raise safety issues. The agronomic, phenotypic and compositional characteristics of maize DAS-40278-9 tested under field conditions revealed no differences between maize DAS-40278-9 and its non-genetically modified (GM) comparator that would give rise to food and feed or environmental safety concerns. There were no concerns regarding the potential toxicity and allergenicity of the newly expressed protein AAD-1, and no evidence that the genetic modification might significantly change the overall allergenicity of maize DAS-40278-9. The nutritional characteristics of maize DAS-40278-9 are not expected to differ from those of non-GM maize varieties and no post-market monitoring of food/feed is considered necessary. Maize DAS-40278-9 is as nutritious as its non-GM comparator and other non-GM commercial varieties. There are no indications of an increased likelihood of establishment and spread of occasional feral maize DAS-40278-9 plants, unless these plants are exposed to the intended herbicides. However, this will not result in different environmental impacts compared to conventional maize. Considering

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[3] http://www.efsa.europa.eu/sites/default/files/assets/independencerules2014.pdf

the scope of the application, interactions with the biotic and abiotic environment were not considered an issue. Risks associated with the unlikely but theoretically possible horizontal gene transfer from maize DAS-40278-9 to bacteria were not identified. The post-market environmental monitoring plan and reporting intervals are in line with the scope of the application. In conclusion, the EFSA GMO Panel considers that the information available for maize DAS-40278-9 addresses the scientific comments raised by the Member States and that maize DAS-40278-9, as described in this application, is as safe as the non-GM comparator and non-GM maize reference varieties with respect to potential effects on human and animal health and the environment in the context of the scope of this application.

The draft opinion was discussed in the EFSA GMO Panel Standing Working Group meetings and was presented to the EFSA GMO Panel for a first reading at its 100th Plenary meeting.

The EFSA GMO Panel voted unanimously in favour of adopting this scientific opinion, which will be published on the EFSA website at EFSA Journal.

The chair invited observers to ask questions on this agenda item.

An observer requested information on how conclusions on composition and processing can be drawn in light of the fact that maize is a segregating crop. An EFSA staff member clarified that the data received for compositional analysis are derived from grains that reflect what is placed on the market. In case of segregation the analysis would therefore be done on a mixture of grains reflecting the respective segregation. With regard to conclusions on processing, the following consideration is applied: if there is no relevant difference observed between the GMO and the non-GM counterpart that could impact on processing, than it is concluded that the GMO will behave in processing the same way as the non-GM counterpart.

Another observer requested clarification on the limit dose of 1000 mg/kg body weight per day that is applied in the context of the 28 day toxicity study. EFSA responded that the 28 day toxicity study is used as a hazard identification study. Therefore it is important to increase the dose as much as possible. In line with OECD guidelines, the so-called limit dose of 1000 mg/kg body weight per day should be used if from assessment of other data, no effects would be expected at lower doses. It is not acceptable to choose the highest dose administered in the 28 day toxicity study based on margin of exposure considerations.

Another observer requested clarification why the agenda of this Open Plenary meeting had been changed before the meeting as opposed to the agenda published 6 weeks ahead of the meeting. An EFSA staff member explained that in each plenary meeting, scientific opinions that are still under development ("first reading") and scientific opinions that are ready for final discussion and possible adoption are placed on the agenda. At the time of publication of the first agenda, there were several scientific opinions on applications at an advanced stage of development. It was difficult to predict exactly which ones would be ready for possible adoption, since EFSA was either awaiting answers from applicants to questions posed and/or had not completely finalised the discussion of the application in WGs.

7.2 Application for authorisation of genetically modified soybean DAS-81419-2 for food and feed uses, import and processing in accordance with Regulation (EC) No 1829/2003 submitted by Dow AgroSciences (EFSA-GMO-NL-2013-116) (EFSA-Q-2013-00527)

Soybean DAS-81419-2 was developed by *Agrobacterium tumefaciens*-mediated transformation. It expresses the Cry1F and Cry1Ac proteins to confer resistance to certain lepidopteran species and the PAT protein that confers tolerance to glufosinate ammonium-based herbicides and that was used as a selectable marker gene. The molecular characterisation of soybean DAS-81419-2 did not give rise to safety issues. The agronomic, phenotypic and compositional characteristics of soybean DAS-81419-2 tested under field conditions revealed no relevant differences between soybean DAS-81419-2 and its conventional counterpart that would give rise to any food and feed or environmental safety concerns. There were no concerns regarding the potential toxicity and allergenicity of the newly expressed proteins Cry1F, Cry1Ac and PAT, and no evidence that the genetic modification might significantly change the overall allergenicity of soybean DAS-81419-2. The nutritional value of soybean DAS-81419-2 is not expected to differ from that of non-GM soybean varieties and no post-market monitoring of food/feed is considered necessary. There are no indications of an increased likelihood of establishment and spread of occasional feral soybean DAS-81419-2 plants, unless these plants are exposed to glufosinate ammonium-based herbicides or infested by insect pests that are susceptible to the Cry1F and Cry1Ac proteins. This will not result in different environmental impacts compared to conventional soybean. Considering the scope of this application, interactions with the biotic and abiotic environment were not considered to be an issue. Risks associated with an unlikely but theoretically possible horizontal gene transfer from soybean DAS-81419-2 to bacteria have not been identified. The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of soybean DAS-81419-2. The GMO Panel concludes that the soybean DAS-81419-2 is as safe and as nutritious as its conventional counterpart and the tested non-GM reference varieties in the context of its scope.

The draft opinion was discussed in the EFSA GMO Panel Standing Working Group meetings and was presented to the EFSA GMO Panel for a first reading at its 109th Plenary meeting.

The EFSA GMO Panel voted unanimously in favour of adopting this scientific opinion, which will be published on the EFSA website at EFSA Journal.

The chair invited observers to ask questions on this agenda item.

No questions were asked from observers.

7.3 New sequencing information for DAS-59122-7 maize (EFSA-Q-2016-00506)

The EFSA Panel on Genetically Modified Organisms (GMO Panel) has previously assessed genetically modified (GM) maize DAS-59122-7 as a single event as well as part of several stacked events. These maize events were found to be as safe as their conventional counterparts and other appropriate comparators with respect to potential effects on human and animal health, and the environment. On 26 July 2016, the European Commission received from Pioneer new nucleic acid sequencing data on maize event DAS-59122-7 and updated bioinformatic analyses using the new sequencing data. The European Commission tasked EFSA to analyse these data and to indicate whether the previous conclusions of the GMO Panel on the previously assessed GM maize events remain valid. The GMO Panel used the appropriate principles described in its guidelines for the risk assessment of GM plants to analyse the received data. The new sequencing data indicated three base pair (bp) differences compared to the sequencing data originally provided; two located in a non-coding region of the insert and one located in the 5' genomic flanking region. These base pairs reported as differences in the new nucleic acid sequencing data on maize event DAS-59122-7 had already been present in the original plant material used for the risk assessment. Thus, with the exception of bioinformatics analyses, the studies performed for the risk assessment remain valid. The new sequencing data and the bioinformatic analyses performed on the new sequence did not give rise to safety issues. Therefore, the GMO Panel concludes that the original risk

assessment of event DAS-59122-7 as a single and as a part of stacked events remains valid.

The EFSA GMO Panel voted unanimously in favour of adopting this scientific opinion, which will be published on the EFSA website at EFSA Journal.

The chair invited observers to ask questions on this agenda item.

An observer requested information on the next steps following the adoption of this document. A representative of the European Commission explained that no further steps will be taken at the commission level, since the EFSA concluded that the sequencing errors had no impact on the previous outcome of the safety assessment for this event.

Another observer asked if EFSA had also considered consequences of this sequencing error for the detection method, and if EFSA has investigated the cause of the sequencing error. EFSA responded that it has not investigated a possible impact on the detection methodology since detection of GM events is in the hands of the Member States and the European Commission and out of the remit of EFSA. The European Commission confirmed that JRC (EURL) is verifying this. EFSA has also not investigated the specific cause of the sequencing error that has occurred in the past, but has focused on the assessment of its safety relevance. In general, it can be considered that the sequencing methodology has considerably improved over the years, and could therefore in some cases lead to more accurate results now as opposed to results obtained years ago.

7.4 Application for authorisation of genetically modified cotton GHB614 x LLCotton25 x MON 15985 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Bayer (EFSA-GMO-NL-2011-94 (EFSA-Q-2011-00134)

The GMO Panel discussed the draft scientific opinion, specifically the sections on molecular characterisation, comparative assessment, food/feed safety assessment and environmental risk assessment. Further discussion is needed.

The chair invited observers to ask questions on this agenda item.

An observer requested information on the genetic distance between the GM plant and its conventional counterpart. EFSA replied that there is no formal cut-off value established. In this specific case there was more than 95% genetic similarity (at the level of alleles) which has been obtained by a series of back-crosses with a recurrent parent. EFSA requires in any case the submission of a detailed breeding tree to be able to evaluate the degree of genetic similarity.

An observer asked how the 2006 Guidance document for the risk assessment of genetically modified plants and derived food and feed[4] and 2007 Guidance Document for the risk assessment of genetically modified plants containing stacked transformation events[5] were applied to the application EFSA-GMO-NL-2011-94. EFSA explained that the principles laid down in the 2006 guidance document for the risk assessment of GM plants are maintained in the 2007 guidance document on stacked events, but that the document on stacked events includes additional guidance specific to stacked events. Consequently, both guidance documents were taken into account during the risk

[4] EFSA Panel on Genetically Modified Organisms, 2006. Guidance document for the risk assessment of genetically modified plants and derived food and feed by the Scientific Panel on Genetically Modified Organisms (GMO) - including draft document updated in 2008. EFSA Journal 2006;4(4):99, 105 pp. doi:10.2903/j.efsa.2006.99

[5] EFSA Panel on Genetically Modified Organisms, 2007. Guidance Document for the risk assessment of genetically modified plants containing stacked transformation events by the Scientific Panel on Genetically Modified Organisms (GMO). EFSA Journal 2007;5(7):512, 5 pp. doi:10.2903/j.efsa.2007.512

assessment. Subsequently, the 2007 Guidance Document on stacked events was replaced by the Guidance for risk assessment of food and feed from genetically modified plants[6] in which specific requirements for stacked events are incorporated in the relevant sections.

8 New mandates

8.1 Applications under Regulation (EC) No 1829/2003

One application was received as follows:

Application for authorisation of genetically modified maize MZHG0JG for food and feed uses submitted under Regulation (EC) No 1829/2003 by Syngenta (EFSA-GMO-DE-2016-133) (EFSA-Q-2016-00583)

8.2 Annual PMEM reports

A new request was received as follows: Request to assess the annual post market monitoring (PMEM) report of genetically modified maize MON 810 for the 2015 cultivation season provided by Monsanto (EFSA-Q-2016-00690).

8.3 Other Requests and Mandates

None.

9 Feedback from the Scientific Committee/the Scientific Panel, Working Groups, EFSA and the European Commission

9.1 Scientific Committee and other Scientific Panels

A Panel member provided an update on the progress of the Guidance Document on biological relevance. The Panel was also informed that a Guidance Document on reopening opinions is being developed and will be discussed at the next meeting of the Scientific Committee.

9.2 EFSA including its Working Groups/Task Forces

9.2.1 Feedback from the Allergenicity public consultation

The Chair of the Allergenicity Working Group provided an overview on the procedural steps and the content of the draft Guidance Document on allergenicity assessment of genetically modified plants. A GMO scientific officer provided an update on the public consultation that closed on 25 September and informed that 199 comments had been received.

9.3 European Commission

The representative from the European Commission provided feedback on applications:

No new authorisation was granted since the GMO Plenary meeting of 21-22 September.

EFSA will be asked to present the recently adopted applications on GM soybean 305423 x 40-3-2 (EFSA-GMO-NL-2007-47), GHB119 (EFSA-GMO-NL-2011-96) and GM maize Bt11 x 59122 x MIR604 x 1507 x GA21 (EFSA-GMO-DE-2011-99) to the PAFF Committee at its November meeting.

An update was provided on the recent activities concerning the new breeding techniques.

[6] EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on Guidance for risk assessment of food and feed from genetically modified plants. EFSA Journal 2011;9(5): 2150. [37 pp.] doi:10.2903/j.efsa.2011.2150.

10 Other scientific topics for information and/or discussion

10.1 Prometheus protocol and PMEM reports on maize MON810

A scientific officer of the GMO Unit presented the status of the project to develop a protocol that can be used to assess the annual PMEM activities on the cultivation of Lepidoptera-active Bt-maize events following the principles and processes illustrated in EFSA Prometheus project (PROMoting METHods for Evidence Use in Science).

The chair invited observers to ask questions on this agenda item.

An observer asked how information on spraying of Bt pesticides is included in this project. EFSA responded that such a crop management practice would be picked up during a survey conducted with farmers cultivating Bt maize in Europe ("farmer questionnaire"). The outcome of this survey is submitted as part of the data package supporting the annual PMEM report. In addition, EFSA remarked that Bt sprays are rarely used in maize since they are not effective enough to protect the crop from corn borers which are the target pests. Another observer asked if the use of Bt sprays by farmers is also monitored. EFSA responded that this is not the case. Another observer asked if the protocol could also include other sources of evidence than the ones presented. EFSA responded that the protocol is flexible, and could be adapted to other sources of evidence. Furthermore, EFSA clarified, that the application of the Prometheus approach is currently in a testing phase, and that at the end of this testing phase EFSA will decide if the approach should be applied routinely.

11 Answers to questions from Observers (in application of the EFSA Guidelines for Observers)

a. Observers were invited to submit questions for the GMO Panel Plenary meeting at the time of registration. These questions, and the corresponding answers, are listed below:

1. "Which role does the Panel envisage for itself in the field of international harmonization of risk assessment approaches for GMOs?"

EFSA continuously tries to improve the quality of its risk assessment by interacting with international risk assessment bodies. This includes, upon delegation from the EC, attending discussion groups or workshops on diverse scientific and risk assessment topics (OECD, FAO, WHO, Cartagena protocol), public consultation on new guidelines produced by the EFSA GMO panel and interactions with other risk assessment bodies in the frame of bilateral meetings or workshop and conferences organised by EFSA. It should be noted that EFSA is bound to act within the European legislative framework which includes detailed requirements for the GMO risk assessment.

2. "Could the work field of the GMO Panel be broadened in the near future with the advent of new technologies similar to GMOs such as genome editing, synthetic biology, etcetera?"

EFSA assesses applications in accordance with the current applicable legislation. When a technique produces a GMO falling under the scope of Directive 2001/18, the GMO unit will be mandated to assess such GMO and respective products before marketing.

3. "What future self-tasking activities of the GMO Panel are in the pipeline, i.e. what other topics can we expect outputs on?"

The EFSA GMO panel closely follows the latest developments in risk assessment and the use of new scientific techniques. Whenever an update or improvement of a current

guideline is warranted, the Chair of the EFSA GMO panel may ask EFSA to initiate a self-tasking activity. Furthermore, technical information or clarifications of current guidance documents can be provided, as needed, for example following discussions with different stakeholders (e.g. note to the guidance on Horizontal Gene Transfer). On-going developments include the update of the Guidance Document on allergenicity (self-tasking activity) and the development of Guidance Document on the Low Level presence of GMOs (request from the European Commission). Both are expected to be completed in 2017. At this point, no new self-tasking activities are planned.

b. Observers were also invited to spontaneously ask questions at the GMO Plenary meeting. These questions, and the corresponding answers, are listed below:

An observer asked if EFSA offers the possibility of pre-submission enquiries on specific dossiers. EFSA explained that for the time being, pre-submission enquiries on specific dossiers are not offered. However, EFSA has published – and is continuously updating – an EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products[7] where, for example, different possibilities on obtaining information on guidance documents and procedural aspects in the pre-submission phase are included.

Another observer enquired about the different types of EFSA outputs, in particular about an output type entitled "Technical Report". EFSA explained that a technical report is an output prepared by EFSA staff and adopted by EFSA. Usually this type of output is chosen for technical clarifications, descriptions of state-of-the art, descriptions of data collections, evaluation of scientific literature, and similar. A technical report is usually completed faster than a panel output. In the GMO frame, technical reports are for example used to evaluate scientific literature or smaller data packages.

Another observer requested information on the implementation of the post market monitoring (PMM) recommended by EFSA in relation to GM plants with enhanced fatty acid profile. In particular, the observer wanted to know whether a detailed protocol was available on how the PMM should be done. A representative of the EC explained that according to the authorisation decision the first step is to check whether any import of relevant products (in this case oils with enhanced fatty acid profile and soybeans for crushing) takes place. So far, this was not the case. If any imports were to occur, applicants would have additional obligations under the authorising decisions. EFSA will be consulted with regard to the collected data and the need for a more detailed monitoring protocol.

An observer enquired about the next steps regarding the review of the mandatory requirement for the 90 day animal feeding study with whole food/feed in the Implementing Regulation 503/2013 and that is foreseen to be reviewed by the EC and Member States during 2016. A representative of the EC responded that the Commission is working on this. However, no concrete time line for this review can be given at this stage.

Several observers asked questions on the advancement of activities in relation to the determination of the legal status of the New Breeding Techniques (NBT). A representative of the European Commission clarified that the EC is in the process of mandating the Scientific Advisory Mechanism (SAM) to elaborate a state-of-the-art scientific document on NBTs building on earlier work done by various bodies. This document should further support the ongoing debate. In a separate matter related to an

[7] European Food Safety Authority, 2015. EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products. EFSA Supporting Publication 2015; 12(3):EN-777, 26 pp. doi:10.2903/sp.efsa.2015.EN-777

ongoing legal procedure at the European Court of Justice, invoked by France regarding the exclusion of organisms produced by mutagenesis from the scope of the GMO legislation, the EC will support the Court by responding to questions should they arise.

An observer asked why for items 7.1 and 7.2 there seems to be not much discussion in the EFSA GMO Panel. The Chair of the EFSA GMO panel responded that more discussion on some aspects of these opinions took place in the Working Groups and in a previous Panel meeting where draft versions of these opinions had been presented for a first reading.

An observer asked how the EFSA GMO Panel takes into consideration new scientific evidence. The Chair of the EFSA GMO panel and EFSA Scientific Officers responded that the Panel and EFSA continuously updates the risk assessment to new developments in science. A current case is the update of key procedures related to the risk of allergenicity. In this case, EFSA initiated a new Working Group producing a new guidance document that is currently under consultation.

Annex I

List of observers attending the GMO Panel Plenary meeting
26-27 October 2016

	Last Name	First Name	Company
1	ALCALDE	Esteban	Syngenta
2	BERBEN	Gilbert	Centre Wallon de Recherches Agronomiques
3	BERNARD	Cristina	Limagrain - Vilomorin & Cie
4	BOVERS	Marjan	COGEM
5	CAERS	Wim	Tate & Lyle Plc
6	CATALLOZZI	Marina	AGCM - Autorità Garante della Concorrenza e del Mercato
7	CNUDDE	Filip	Dow AgroSciences
8	COPPENS	Fanny	Scientific Institute of Public Health
9	DELZENNE	Pascale	Monsanto
10	DESIATO	Rosanna	Istituto Zooprofilattico Sperimentale PLVA
11	FERNANDEZ CANTON	Rocio	Monsanto Europe S.A.
12	FERRER	Clara	Animal Health Border Inspection
13	GEORGIEVA	Violeta	EuropaBio
14	HOSNI	Taha	Bayer
15	HUTCHISON	Paul	Agra Europe
16	KOSTOLIANOVA	Petra	EuropaBio
17	LARDINOIS	Kelly	Federal Public Service Public Health, Food Chain Safety and Environment
18	LEGRIS	Gaston	Dow AgroSciences
19	LIPUT	Camilla	Bayer Cropscience
20	MENNE	Bruno	SAFE- Safe Food Advocacy Europe
21	MERRIMAN	George	DuPont Pioneer
22	NIGRO	Sara	Syngenta
23	PIC	Emmanuelle	Anses - Risk Assessment Department
24	PODEVIN	Nancy	Pioneer
25	QUINONES ROJAS	Barbara	Embassy of Argentina to the EU
26	REDENBAUGH	Mark Keith	Arcadia Biosciences, Inc.
27	SERT	Valerie	DuPont Pioneer
28	TROLLOPE	Kate	EU Food Policy
29	WAßMANN	Friedrich	Federal Agency for Nature Conservation