

Scientific Panel on GMO

Minutes of the 121th Plenary meeting of the Scientific Panel on GMO

7-8 March 2018, Parma

(Agreed on 22 March 2018)

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, Fabien Nogué, Christophe Robaglia, Nils Rostoks, Jeremy Sweet, Christoph Tebbe, Francesco Visioli and Jean-Michel Wal

- **European Commission representatives:** Béatrice Marquez-Garrido and Hans Moons (DG SANTE)

- **EFSA:**

GMO Unit: Fernando Álvarez, Michele Ardizzone, Herman Broll, Giacomo De Sanctis, Yann Devos, Silvia Federici, Antonio Fernández Dumont, Andrea Gennaro, José Ángel Gomez Ruiz, Marina Koukoulanaki, Anna Lanzoni, Sylvie Mestdagh, Nikoletta Papadopoulou, Claudia Paoletti, Konstantinos Paraskevopoulos, Matthew Ramon, Kamila Sflugier Tollik, Elisabeth Waigmann and Claudine Ziegelmeier.

Other EFSA Units/Directorates: none.

- **Observers (in application of the guidelines for observers):**

- **Attending physically in Parma:** Pascale Delzenne (Monsanto), Karen Holt (Syngenta), Petra Kostolaniova (EuropaBio), Maica Martinez Parrilla (Bayer), Michele Milizia (ISA, s.p.a.), Hong Moon (Monsanto), Ignazio Pau (ISA, s.p.a.), Valérie Sert (DuPont Pioneer), Lisette van der Knaap (COGEM)
- **Attending via web streaming:** Oksana Apanasets (Bayer), Argyrios Boulis (Ministry of Rural Development and Food), Filip Cnudde (EMEA Dow DuPont), Francesco Damiani (CNR), Joyce Ebebeinwe (Health of Mother Earth Foundation - HOMEF), Mikael Egebjerg (DTU Food), Anikó Ézsiás (NEBIH Hungary), Rachel Gast (Syngenta), Linda Grešová (State Veterinary and Food Institute), Taha Hosni (Bayer), Gijs A. Kleter (RIKILT Wageningen University and Research), Sara Nigro (Syngenta), Jelena Petrovic (Center for Food Analyses), Nancy Podevin (Pioneer Overseas Corporation), Romaan Raemaekers (Syngenta), Petra Richl (Eurofins GeneScan GmbH), Valerie Sert (DuPont Pioneer), Giovanni Staiano (ISPRA Ambiente), Sonia Tessier (Heath and Safety Executive UK), Eszter Timar (NEBIH), Nico van Belzen (ScienceConsult BV), Petra Vanková (Food Safety Authority of the Slovak Republic), Christine Wandelt (BASF Plant Science Company GmbH), Irina Wenderoth (BASF Plant Science)

- **Others:** none.

1. Welcome and apologies for absence

The Chair of the GMO Panel welcomed all the participants. Apologies were received from Antoine Messéan and Nick Birch for 8 March.

2. Brief introduction of Panel members and Observers

The Chair of the GMO Panel warmly welcomed the observers who travelled to Parma to participate to this plenary meeting. Members from the GMO Panel and the GMO Unit as well as on-site observers briefly introduced themselves through a tour de table.

The Chair also welcomed the observers who will follow the discussions through web-streaming.

3. Adoption of agenda

The agenda was adopted without changes. The Chair of the GMO Panel reminded that all agenda items are now open to observers.

4. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², 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. Philippe Guerche did not participate to the discussion on agenda item 7.2 due to a specific conflict of interest.

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

5. Presentation of the Guidelines for Observers

A member of the GMO Unit presented the EFSA Guidelines for Observers that were also provided ahead of the meeting (available [here](#)).

6. Report on written adoption procedure since 120th Plenary meeting

The minutes of the 120th Plenary meeting held on 24-25 January 2018 were adopted by written procedure on 8 February and subsequently published on 9 February on the EFSA website at: [Event: 120th plenary meeting of GMO Panel](#).

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

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/sites/default/files/assets/independencerules2014.pdf>

7.1 Assessment of genetically modified cotton GHB614 x LLCotton25 x MON15985, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-94) ([EFSA-Q-2011-00134](#))

Cotton GHB614 x LLCotton25 x MON15985 was developed to express herbicide tolerance and insect resistance traits.

The GMO Panel was reminded that a draft opinion on application EFSA-GMO-NL-2011-94 had already been brought to its attention in October 2016³. Since then the Panel and its standing Working Groups continued their risk assessment of cotton GHB614 x LLCotton25 x MON15985 to come up with a revised text of the scientific opinion proposed for discussion and possible adoption by the Panel.

The GMO Panel reviewed the text before unanimously adopting the scientific opinion at stake.

The Chair invited on-site observers to ask questions on this agenda item, but there were no questions.

7.2 Assessment of genetically modified soybean MON87751 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.

A member from the GMO Unit explained that application EFSA-GMO-NL-2014-121 was the first GMO dossier submitted to EFSA after the entry into force of Regulation (EU) No 503/2013⁴. In this respect application EFSA-GMO-NL-2014-121 should comply with the legal requirements laid down in Regulation (EU) No 503/2013.

The GMO Panel was reminded that the text of the scientific opinion was already discussed at the last plenary open to the public that took place in October 2017. Since October 2017 the GMO Panel and its standing Working Groups complemented specific sections of the opinion including human and animal dietary exposure assessments.

Consequently the GMO Panel reviewed the new text, including sections dedicated to acute and chronic dietary assessments. The GMO Panel was informed that the standing Food & Feed Working Group recently requested additional information to finalize its toxicological assessment.

The Chair invited on-site observers to ask questions on this agenda item. An observer asked for information about a forthcoming explanatory note on the dietary exposure assessment that was referred to by a member of the GMO Unit during the discussion. The member from the GMO Unit recalled a previous EFSA statement⁵ on how to use the EFSA Comprehensive European Food Consumption Database for estimating dietary exposure to genetically modified foods. The upcoming note will aim at supplementing the aforementioned statement based on the currently gained experience with acute and chronic dietary exposure assessments.

An observer asked for clarifications on EFSA approach towards the implementation of Article 6 of Regulation (EU) No 503/2013 and the applicants' obligation to submit studies that would be produced during the risk assessment. Question was illustrated with

³ <http://www.efsa.europa.eu/sites/default/files/event/161026-m.pdf>

⁴ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:157:0001:0048:EN:PDF>

⁵ European Food Safety Authority, 2015. Use of EFSA Comprehensive European Food Consumption Database for estimating dietary exposure to genetically modified foods. EFSA Journal 2015;13(2):4034, 11 pp., doi:10.2903/j.efsa.2015.4034

reference to the standard broiler studies that are not required in the EU but still provided by applicants because produced for other jurisdictions.

The Head of the GMO Unit made clear that all studies received in support to GMO applications are subject to a thorough assessment by the GMO Panel, independently on whether they are legally required, requested by EFSA and the GMO Panel, or submitted spontaneously by applicants. Subsequently these studies are reported into the relevant sections of the scientific opinions.

In addition to the initial information package collected prior to submission of the dossier, applicants should also report any additional studies that 'might influence the risk assessment' and that would be made available after submission, in order to comply with Article 6 of Regulation (EU) No 503/2013.

7.3 Assessment of genetically modified maize MON87403 for food and feed uses submitted under Regulation (EC) No 1829/2003 (application EFSA-GMO-BE-2015-125) ([EFSA-Q-2015-00430](#))

Maize MON87403 was developed to increase ear biomass at the early reproductive phase through the expression of a modified *Athb17* gene from *Arabidopsis thaliana* in maize, encoding a plant transcription factor of the HD-Zip II family.

The GMO Panel already discussed the specificities of the intended trait and the implications on the risk assessment. At its last meeting the GMO Panel tasked its standing Working Groups to finalise the draft opinion for possible adoption in due time.

Owing to the novelty of the techniques used, the GMO Panel emphasized that molecular characterisation of maize MON87403 was performed by Next Generation Sequencing (NGS) and welcomed this new approach.

The GMO Panel went through the text of the scientific opinion and, where needed, revised it. The GMO Panel adopted the scientific opinion on application EFSA-GMO-BE-2015-125 so that it becomes the first GMO dossier adopted under Regulation (EU) No 503/2013.

The Chair invited on-site observers to ask questions on this agenda item. An observer asked how the GMO Panel plans to tackle the dietary exposure assessment of maize MON87403. The Head of the GMO Unit clarified that since the scientific opinion was adopted, the adopted text pertaining to dietary exposure assessment is final. However, the Chair of the Panel clarified that the Food and Feed Working Group will further discuss dietary exposure assessment to refine the approach and its presentation in future opinions.

7.4 Assessment of new additional information related to the application for authorisation of food and feed containing, consisting and produced from genetically modified maize 5307 (adopted application EFSA-GMO-DE-2011-95) ([EFSA-Q-2017-00052](#))

A member from the GMO Unit sets the scene by presenting the terms of reference of the present mandate from the European Commission.

On 16 April 2015 the GMO Panel was not in the position to conclude its risk assessment of maize 5307 submitted under application EFSA-GMO-DE-2011-95 (scientific opinion is available at <https://www.efsa.europa.eu/it/efsajournal/pub/4083>). The applicant submitted to the European Commission a study addressing the missing information. On 23 December 2016, the European Commission asked the GMO Panel to supplement its previous evaluation of maize 5307 in the light of this new information.

The GMO Panel reviewed the scientific opinion supplementing the initial risk assessment of maize 5307 and concluded that the new information does not raise any new safety

concern and that maize 5307 is as safe and nutritious as its conventional counterpart. The opinion was unanimously adopted.

The Chair invited on-site observers to ask questions on this agenda item. An observer asked whether subacute toxicological studies with a design similar to that of the additional study under assessment would be considered satisfactory by the GMO Panel. A member of the GMO Unit answered that it is impossible to pre-empt the outcome of any study evaluation. Overall studies submitted to EFSA are assessed on a case-by-case basis subject to full compliance with the EU standards in place.

8. New mandates

8.1 Applications under Regulation (EC) No 1829/2003

Two new applications were received:

- Application EFSA-GMO-RX-012 for the authorisation renewal of food and feed containing, consisting and produced from genetically modified oilseed rape T45 and products other than food and feed containing or consisting of it, authorised under Regulation 1829/2003 (Commission Decision 2009/184/EC).
- Application EFSA-GMO-NL-2018-148 for the placing on the market of genetically modified soybean DP305423 X MON87708 X MON 89788 submitted by Pioneer Hi-Bred International Inc.

8.2 Annual PMEM reports

Since the last meeting of the GMO Panel (minutes here), EFSA did not receive any new mandate from the European Commission related to an annual PMEM report on a GM crop.

8.3 Other Requests and Mandates

Two mandates have been received since last reported in the GMO Panel plenary meeting:

- o Mandate to assess New sequencing information of soybean BPS-CV127-9 ([EFSA-Q-2018-00143](#))
- o Mandate to assess New sequencing information of oilseed rape Ms8 ([EFSA-Q-2018-00142](#))

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

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

9.1.1. Scientific Committee

The Chair of the GMO Panel reported on the 87th Scientific Committee plenary meeting (14-15 February 2018). There is currently no new information that would directly impact the GMO Panel activities.

At EFSA level there are ongoing activities to develop new guidelines on various topics such as the threshold of toxicological concern approach, uncertainty communication, assessment of nanomaterials or genotoxicity of mixtures. A project called RAM-Pro is also progressing with the objective to foster collaboration between Units, Departments and different areas of risk analysis (e.g. development of a generic guidance on the environmental risk assessment).

Minutes of the 87th Scientific Committee plenary meeting will be published on the EFSA website.⁶

9.2 EFSA including its Working Groups/Task Forces

9.2.1 EFSA's 3rd Scientific Conference

A member of the GMO Unit updated the participants on the progress made in the organisation of the EFSA's 3rd Scientific Conference, which will be held in Parma on 18-21 September 2018.

In brief, participants were informed that (1) owing to the already high participation rate, registration is likely to be closed before the deadline; (2) poster abstracts can be submitted until 2nd April 2018.

The conference will be built around two plenary sessions addressing the interface between science and society. In addition various topics such as biological hazards, engaging with society and managing evidence will be discussed in break-out sessions. There will also be room for young scientists to present their researches. Discussions will be broadcasted. For more information the dedicated website of the EFSA's 3rd Scientific Conference can be checked at <https://conference.efsa.europa.eu/>.

In the light of EFSA difficulties to renew the pool of external expertise, a Panel Member asked if EFSA considers other ways to encourage young scientists to engage with EFSA. A member of the GMO Unit explained that there are currently two channels offered to young scientist to collaborate with EFSA: (1) through contracts (grants and procurements); (2) through the European Food Risk Assessment Fellowship Programme (EU-FORA) that gives scientists from national institutes the opportunity to increase their knowledge and hands-on experience in food safety risk assessment.

9.2.2 EFSA Colloquium on the use of omics in risk assessment

A member of the GMO Unit presented the main topics to be covered by a scientific colloquium on the use of omics in risk assessment, which will be held in Berlin, on 24-25 April 2018.

The main objective of the Colloquium is to explore opportunities for integration of datasets produced via specific omics tools.

9.2.3 Sequencing WG

The chair of the GMO Working Group⁷ on 'Sequencing quality'⁸ first reminded the Panel of the terms of reference of the mandate received from the European Commission. In late 2017 the European Commission tasked EFSA to develop a guidance document which will explain the requirements and recommendations for the use of DNA sequencing information in the context of the risk assessment of GMOs with respect to: the sequencing of insert(s) and flanking regions, and the insertion site analysis and generational stability/integrity.

In order to address this very specific request a dedicated Working Group was set up and already met four times. Owing to the importance of the upcoming guidance and the novelty of the topic, stakeholders will be invited to take part to discussions in the frame of a Working Group meeting.

The draft guidance document will be presented to the next Plenary meeting in preparation of a possible adoption before summer 2018.

9.3 European Commission

⁶ <http://www.efsa.europa.eu/en/events/event/180214>

⁷ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁸ <http://www.efsa.europa.eu/en/events/event/171025>

The representative of the European Commission informed the Panel on (1) the appeal committee on two GM maize events (still with no opinion from Member States), and (2) the Standing Committee meeting on Plants, Animals, Food and Feed (PAFF) on 19 March 2018.

At the PAFF committee meeting in March 2018, Member States will be asked to vote on GM sugar beet event H7-1 and EFSA will present the following GMO Panel opinions:

- Scientific opinion supplementing the previous GMO Panel risk assessment of maize Bt11×59122×MIR604×1507×GA21 and its sub-combinations under application EFSA-GMO-DE-2011-99;
- Scientific opinion on renewal application EFSA-GMO-RX-007 (maize NK603 x MON810).

The representative of the European Commission also reported on the recent adoption by the Member States of the directive amending Directive 2001/18/EC on the deliberate release into the environment of GMOs.

10. Other scientific topics for information and/or discussion

None.

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

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

Could the Panel please clarify in which cases it wishes to receive data on forage composition, expression data, etc?

The reason for my asking is that such forage data appear relevant in some but not all cases. Relevant cases in my view are cultivation dossiers (e.g. when crops are grown for forage or the green parts after harvest are used as by-product) and, in the case of import dossiers, for a few crop species for which are already traded as international commodities (alfalfa, grasses) but not for all crop species. Moreover, different varieties of the same crop may have been developed specifically for forage production as opposed to e.g. oilseed production.

To the aforementioned question a member of the GMO Unit provided the following answer:

Regulation (EU) No 503/2013, requires the provision of information and data collected from those parts of the plant relevant to the scope of application, which, when it is a full scope, includes food and feed containing, consisting of and derived from the GM crop under assessment.

With regard to GM feed, the relevant part of the plant which may enter the feed chain as raw agricultural commodities are primarily grains (e.g. maize), beans (e.g. soybean), seeds (e.g. cotton and rapeseed), roots (e.g. sugarbeet). However, the risk assessment must also take into account all known uses linked to current animal feeding practice which may include also other parts of the plant for the production of feed, as in the case of the whole aerial part for maize and soybean or the top and leaves for sugarbeet. These parts of the plant are commonly defined as forage, and their data should be included in the dossier.

EFSA has recently published an explanatory note⁹ (EFSA, 2018) to clarify on a crop-specific basis the principles for an appropriate selection of forage material for risk assessment of GM feed of plant origin.

During the meeting, in addition to the questions from on-site observers addressed above, web-streamers could also pass their questions on the discussion items. Questions received (exact quote from web-streamers) and replies given by Panel member or GMO Unit staff are reported in the table below.

	Questions from web-streamers	EFSA/Panel replies
1	<p><i>Question on application 121:</i></p> <p><i>There is an apparent paradox. Whilst the Panel usually dismisses acute tox studies, their inclusion into the human dietary exposure assessment would impart relevance to them. It raises questions on the usefulness of acute dietary exposure</i></p> <p><i>As regards chronic exposure, the Panel has a good point. The proteins can be considered safe based on the weight of evidence so the "chronic exposure data are "nice to know" (indicating low exposure) rather than "need to know".</i></p>	<p>It was reminded that exposure assessment is mandatory under Regulation (EU) No 503/2013. The strategy to exposure assessment is currently under refinement as regards the approach and its presentation in future opinions.</p>
2	<p><i>Interesting discussion on the safety of a chimeric protein considered to be new. What updates can the Panel give on any horizontal activity with regard to developing guidance for how to test the safety of newly expressed proteins? What lessons can we learn from cases like #95? Has animal testing with newly expressed proteins brought any new information to light so far or would they rather confirm the robustness of the weight of evidence approach?</i></p>	<p>The assessment of the protein expressed in AP95 was done in accordance with the applicable EFSA guidance (2011). The unit indicated that there is no present plan to develop a new guidance to test the safety of newly expressed proteins.</p> <p>However, in the frame of continuous improvement, EFSA will consider scientific development in the field of protein safety assessment, embarking on further developments as needed.</p>
3	<p><i>Supposedly, this conclusion implies that the evidence on 5307 is now conclusive and the European Commission can now proceed with drafting a proposal for its regulatory approval?</i></p>	<p>Absolutely. The initial inconclusive risk assessment of maize 5307 and the newly adopted supplementary statement will be both subject to the standard public consultation organized by the European</p>

⁹ EFSA (European Food Safety Authority), Ardizzone M, Paoletti C, Waigmann E, 2018. Technical report on the explanatory note on the selection of forage material suitable for the risk assessment of GM feed of plant origin. EFSA supporting publication 2018:EN-1366. 9 pp. doi:10.2903/sp.efsa.2018.EN-1366

		Commission. Consequently, according to the standard procedure, a draft decision for placing maize 5307 on the EU market will be proposed to Member States for a vote.
4	<i>Would the Panel find it useful to have the outcomes of research projects on GMO safety assessment methodology presented to them?</i>	The GMO Panel monitors research activities falling within its remit. Research projects that might impact the GMO risk assessment were already presented in the frame of the GMO Network with Member States as well as at the Panel or its standing Working Groups meetings. For example, the outcome of the EU-wide AMIGA project was recently presented to the GMO Panel.
5	<i>Has the Panel taken note of initiatives towards incorporation of safety aspects of a product at an early stage of its development in advance of the regulatory safety testing further downstream? For example, would the Panel feel inclined to help develop guidance for the fields of GMOs and synthetic biology? Currently, there is talk of "safe by design" in nanotechnology and, more generally, responsible research and innovation in research. UNESCO and the French INSERM and Spanish CSIC will start the ARRIGE initiative on responsible genome editing later this month. In my country, we try to extend "safe innovation / safe by design" into the field of synthetic biology. It would be nice to have some European exchange, collaboration and consensus.</i>	It was clarified that EFSA is currently not involved in the development of such guidance documents. The example of the allergenicity assessment was brought up since, with support of bioinformatics data, applicants can screen for new products at a very early stage of their development.
6	<i>Does the Panel have any view on the concept of "familiarity" with certain types of modification? In many opinions with common modifications (e.g. PAT, EPSPS, Cry proteins), there is already implicit reference in the respective sections on safety of traits and newly expressed proteins, yet would it be possible to more categorically exempt modifications from the need of data provision?</i>	It was clarified that the GMO risk assessment is carried out on a case-by-case basis. Even though the Panel has acquired some knowledge in risk assessing recurrent well known proteins, each new transformation event is assessed according to the same standard since extrapolation is not possible.
7	<i>What is the Panel's opinion on the value of bioinformatics of potential new</i>	First of all this is paramount to identify if the potentially expressed

	<p><i>open reading frames (ORFs) within the insert and its flanks if these are unlikely to be expressed? Would an initial analysis of likelihood of expression (e.g. if the insert is fused with part of an intrinsic gene) before sequence comparisons be helpful, you think?</i></p>	<p>peptides may raise safety concerns. Both the likelihood of expression as well as the likelihood to raise safety concerns are considered relevant for the risk assessment. It was acknowledged that the current approach followed by the GMO Panel, which takes into account also CODEX guidelines, will need to be revised in terms of overall requirements including bioinformatics data.</p>
8	<p><i>How are the updates to the 2011 guidance (and hence the implementing regulation annex) going to be incorporated into any new, updated guidance or annex to the regulation?</i></p>	<p>Article 12 of Regulation (EU) No 503/2013 foresees a possible revision of the regulation in the light of latest EFSA developments in GMO risk assessment.</p>
9	<p><i>Given all the different studies performed on RNAi by contractors for the EFSA GMO Panel, does the Panel intend to carry out a self-tasking activity and/or develop any statement, explanation or guidance?</i></p>	<p>EFSA called for external contractors to collect background information on RNAi from three different perspectives: molecular characterisation, food and feed assessment and environmental risk assessment. Final outcomes of all these procurement contracts are expected within the coming months. During its ongoing risk assessment of GMOs with RNAi approach, the GMO Panel already takes into consideration the currently available knowledge.</p>
10	<p><i>Question on AP 125:</i> <i>It appears that the topic of "unintended effects" deserves special attention because this involves a transcription factor, which in theory could exert "off-target" effects, right?</i></p>	<p>It was difficult to put the question into context. In the absence of background information, the reply was that if any unintended effect linked to the new trait was to occur, this would have been identified in the field trials.</p>
11	<p><i>As regards dietary exposure, would it be worthwhile to compare this to the intake of known dietary proteins or protein overall, since this may already provide some context and insight into the small fraction that these new proteins constitute?</i> <i>Would the term "aggregate evidence" be acceptable to avoid confusion with other "weight of evidence" items</i></p>	<p>The use of comparative dietary exposure assessment involving a new protein and a similar protein (in terms of structure and function) known to be commonly consumed can be used to conclude on the safety of the new protein. However, such an approach will carry some uncertainty directly linked to the degree of similarity. This approach is used within EFSA in other areas such as the authorization of food enzymes by the CEF Panel.</p>
12	<p><i>Could the pesticide use influence the</i></p>	<p>A positive answer was given since pesticide use may influence the</p>

	<i>nutritional composition?</i>	physiology and metabolism of the crop. It was acknowledged that this aspect is already part of the GMO risk assessment.
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Moreover, at the end of the meeting, the Chair of the GMO Panel gave an ultimate opportunity to on-site observers for posing questions on what was previously discussed during the meeting. No questions were raised.

12. Any other business

12.1 Explanatory note on the selection of forage material suitable for the risk assessment of GM feed of plant origin

As follow-up to the question received from an observer ahead of the meeting, a member of the GMO Unit presented the principles of the recent explanatory note on the selection of forage material suitable for the risk assessment of GM feed of plant origin.

Regulation (EU) No 503/2013 (IR) requires amongst others, data from raw agricultural commodities entering the feed production and processing chain. Different parts of a plant, i.e. whole grain, bean or seed and forage, may enter the feed chain as unprocessed raw material. Whereas the grain, bean and seed are well defined for each plant, the definition of forage varies on a crop-by-crop basis as the parts likely to enter the feed chain differ among crops. This explanatory note provides a crop-specific definition of forage for maize, soybean, sugarbeet, rapeseed and cotton, mitigating the lack of forage definition in the regulatory context and supporting the appropriate selection of forage material, as required by the Implementing Regulation.

The explanatory note was published on 29 January 2018 and is available at <http://www.efsa.europa.eu/en/supporting/pub/1366e>

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 7.2 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 submitted to EFSA under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-NL-2014-121), in his capacity as 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 Processes¹⁰ and the Decision of the Executive Director on Declarations of Interest¹¹, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of the agenda item 7.2.

¹⁰ <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

¹¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>