GENETICALLY MODIFIED ORGANISMS UNIT

Network on Risk Assessment of GMOs

Minutes of the 11th meeting (TELE)

TELE-conference, 03 July 2020

(Agreed on 22 July 2020)[1]

Participants

- **Network Representatives of Member States (including EFTA Countries):**

Country	**Name[2]**
Austria	Marion Dolezel, Markus Wögerbauer
Belgium	René Custers, Adinda De Schrijver
Bulgaria	Tzveta Georgieva, Antoniya Dimitrova, Dimitar Djilianov
Cyprus	
Croatia	Sanja Miloš, Renata Hanzer
Czech Republic	Zuzana Doubkova,
Denmark	Jan Pedersen
Estonia	Teele Jairus
Finland	Kirsi Tormakangas
France	Nathalie Arnich, Catherine Golstein, Emmanuelle Pic,
Germany	Andrea Scheepers, Wolfram Reichenbecher
Greece	Margarita Karavangeli, Argyrios Boulis, Dionysia Stefanitsi
Hungary	Rita Andorkó
Ireland	Patrick O'Mahony

1 Minutes should be published within 15 working days of the final day of the relevant meeting.

2 Indicate first full name and them surname (John Smith) throughout the document

Italy	Marzia De Giacomo
Latvia	Lelde Grantina-Ievina
Lithuania	
Luxembourg	Luc Schuler
Malta	
Netherlands	Boet Glandorf, Cynthia van Rijn, Gijs A. Kleter
Poland	Slawomir Sowa
Portugal	
Romania	
Slovakia	Sevcikova Zuzana
Slovenia	Bostjan Petelinc, Batic Martin
Spain	Félix Ortego, Carmen Cuadrado,
Sweden	Johan Ålander
United Kingdom	
Iceland	
Liechtenstein	
Norway	Ville Erling Sipinen
Switzerland	Martin Schrott

- **Observers**

Nur Koyuncu (Turkey), Ana Velimirovic (Montenegro), Aleksej Tarasjev (Serbia).

- **European Commission:**

Hans Moons, Ilaria Ciabatti, (DG SANCO)

- **Hearing experts and EFSA GMO Panel members:**

Tamas Dalmay, Leslie Firbank, F. Javier Moreno, Hanspeter Naegeli, Fabien Nogué, Nils Rostoks.

- **EFSA:**

GMO Unit: Elisabeth Waigmann (Chair), Maeve Cushen, Yann Devos, Silvia Federici, Antonio Fernandez Dumont, Andrea Gennaro, Sonia Hernandez Valero, Dafni Maria Kagkli , Anna Lanzoni, Maria Neri Franco, Yustina Anna -Olshevska Grigorov, Nikoletta Papadopoulou, Konstantinos Paraskevopoulos, Riccardo Vriz.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Ewen Mullins (GMO Panel member). The chair explained that due to current COVID-19 restrictions, this meeting is being conducted fully remotely. To take this situation into account, the meeting was exceptionally shortened to a half day meeting, with a focus on the 3 biotechnology mandates for which the public consultation was recently concluded.

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes of the 10th meeting of the Network on risk assessment of GMOs held on 18-19 June 2019, Parma.

The minutes were agreed by written procedure on 12 July 2019 and published on the EFSA website[3].

The Chair explained that, in line with the EFSA procedures related to meeting minutes, the GMO Network experts will receive the minutes shortly after the meeting, with a limited time to provide comments.

4. Topics for discussion

Agenda item 3: Mandate on genome editing

Tommaso Raffaello (EFSA scientific officer) briefly summarized the content of the presentation given during the GMO open plenary (1st July 2020) on the mandate on plants developed via SDN-1, SDN-2, and ODM methods (hereafter, mandate on genome editing).

For agenda item 3.1, some comments and clarifications were raised by some network members. Gijs A. Kleter (Netherlands) asked whether EFSA would receive a follow up mandate from EC to generate a new guidance document for the risk assessment of genome edited plants. Adinda De Schrijver (Belgium) suggested that the scientific value of the mandate would have been higher if SDN-1, SDN-2, and ODM techniques had been compared to conventional breeding techniques, instead to SDN-3. A representative of the European Commission clarified that since the comparison was done with conventional breeding in the SDN-3 opinion, the same rationale was followed for the SND-1 SDN-2, and ODM mandate in order to build on the existing work and to assess whether the same approach and conclusions as detailed in the SDN-3 opinion would be still applicable. Furthermore, Boet Glandorf (Netherlands) indicated that the comparison with SDN-3 techniques is not very informative since this focuses the considerations in the SDN-1 SDN-2 and ODM opinion on the presence/absence of exogenous DNA rather than providing the overall approach that EFSA would take for the risk assessment of genome edited plants.

For agenda items 3.2, 3.3, and 3.4, Emmanuelle Pic (France), Kleter Gijs A. (Netherlands), and Wolfram Reichenbecher (Germany) presented a summary of their comments on the draft opinion on the mandate on genome editing. A brief abstract was provided by the presenters and it is included below.

Presentation from Emmanuelle Pic (France) for agenda item 3.2: The consultation on the GMO Panel's draft scientific opinion on genome editing was put back in the context of the judgement of the Court of Justice of the European Union (case C-528/16) of 25 July 2018 and the ruling of the French Conseil d'État of 7 February 2020, as regards the exact list of techniques that will be excluded from the scope of Directive 2001/18/EC. Then, Emmanuelle Pic indicated that the main concerns raised by Anses related to the presence or not of the SDN module in the final product and the off-target effects. Regarding the first issue, Anses considered that the transient expression of the SDN or the removal of the SDN genes by segregation in case of their stable integration will have to be demonstrated. When

[3] Available at https://www.efsa.europa.eu/sites/default/files/event/190618-m.pdf

this removal is not feasible, the associated potential hazards need to be studied. Concerning the off-targets, there is not yet a scientific consensus, especially in plants, to exclude new hazards, which need to be studied. Anses proposed the use of whole genome sequencing associated with a targeted analysis to characterise the final products and stressed the need of research efforts to develop methods and tools for the identification of off-targets even in the most complex cases.

Presentation from Kleter Gijs A. (Netherlands) for agenda item 3.3: The recently published consultation document with the GMO Panel's draft opinion on SDNs 1&2 carries the implicit conclusion that there is a lesser likelihood of unintended effects caused by the application of these techniques as compared to SDN-3 and more traditional techniques of plant breeding. The reasons underlying this conclusion are the lack of possible disruption of host genes & regulatory elements, and the comparability of off-target mutations, by nature and frequency, to those induced by other, more traditional forms of mutagenesis and breeding. The draft opinion mentions that even less experimental data may be needed than for SDN-3. Whilst the presenter by and large agrees with these conclusions, the opinion, bound by its remit, is not specific as to which specific data are needed for SDN-1/2- and ODM-modified plants. For the identification of unintended effects, various data are evaluated routinely in risk assessment, such as molecular characterization, and extensive compositional agronomic, phenotypic and compositional data, and whole-product feeding trials. Arguably, all or part of these data can be skipped. The question is raised what follow up may be given in the form of more detailed guidance, possibly as a tiered approach, for the assessment of SDN-1/2 and ODM-modified plants.

Presentation from Wolfram Reichenbecher (Germany) for agenda item 3.4: Wolfram Reichenbecher from the Federal Agency for Nature Conservation welcomed that the issue of hazards of SDN interventions has been taken up by EFSA, also with a view to the ECJ ruling as background for the opinion. While EFSA's draft opinion focuses on the question of whether foreign genes or exogenous DNA have been inserted and on intended molecular changes, other important issues are not covered: (i) Multiplexed genome editing allows for deeper genomic interventions and with several examples in plants since EFSA's opinion on SDN-3 was published in 2012; (ii) on-target effects of genome editing at the target region have been described also for plants, but have probably been overlooked in studies due to the application of short-ranged methods (PCR, NGS); (iii) conventional breeding and genome editing are compared in the draft opinion and in EFSA's opinion on SDN-3 in terms of the number and type of mutations, but not in terms of the overall approach to achieve a trait or where mutations occur and (iv) SDN interventions involve several steps. It was concluded that there is an unbalance which should be resolved, because the draft opinion concentrates on the specificity of genome editing, but does not cover its molecular power, potential and impact.

Following the three presentations, some comments were raised (agenda item 3.5). Nils Rostoks (GMO Panel member, chair of the MC WG) highlighted the fact that molecular targets are also present in conventional breeding and that, even though the selection can indeed be based on the phenotype, any phenotypic effect is based on modifications in the genes. A similar observation was raised by Patrick O'Mahony (Ireland). Gijs A. Kleter (Netherlands) suggested that off-target mutations potentially present in the genome of the edited plant will be lost during segregation following backcrossing. Andrea Scheepers (Germany) asked for a

clarification on the meaning of the expression "*deep genomic intervention"* which Wolfram Reichenbecher introduced in his presentation. Wolfram Reichenbecher clarified that the expression "*deep genomic intervention"* does not represent an objective quantification but rather an idea or a concept describing a situation where the use of the genome editing process impacts several genes (for example, when a gene family or multiple genes involved in metabolic pathways are modified or altered at the same time).

Regarding Wolfram Reichenbecher's presentation, Fabien Nogué (GMO Panel member) highlighted the fact that not only genome editing techniques are able to create specific associations in the genome, but also other techniques such as marker-assisted selection. Therefore, Fabien Nogué asked whether the risk assessment of GM plants produced by genome editing and by molecular marker assisted selection should follow the same approach. Wolfram Reichenbecher remarked that there is a continuum between conventional breeding and genome editing; moreover, genome editing is a more powerful tool for genome intervention which can create complex traits in different ways compared to conventional breeding approaches.

Emmanuelle Pic (France) further commented that the off-target issue is not extensively addressed in the related section of the scientific opinion on SDN-1, SDN-2, and ODM and should be strengthened. Emmanuelle Pic expressed the idea that the applicant should characterise the product more in details, for example by using WGS to analyse specific genomic loci which could represent hotspots for off-target mutations.

In response to Emmanuelle Pic's comment, Fabien Nogué (GMO Panel member) commented that off-target mutations will be removed by backcrossing and in any case will be of the same type as those obtained through conventional breeding. Tamas Dalmay (GMO Panel member) also responded to the comment on the off-targets section in the opinion, highlighting the fact that DNA alterations fall into a limited type of categories which will be of the same type even when using different approaches. Therefore, it is not possible to say whether the mutation is the result of the gene editing intervention or whether the mutation is spontaneous.

Tommaso Raffaello (EFSA scientific officer) presented the questions for discussion which were already communicated to the GMO network members prior to the meeting and explained the underlying rationale for posing them (agenda item 3.6). The following questions were tabled for discussion:

1. The application of SDN-based methods for genome editing in plants can induce off-target mutations. What are the new aspects, if any, for risk assessment of off-targets specific to genome-edited plants that should be taken into consideration? Would the current EU risk assessment guidance for GM plants be sufficient to risk assess off-target effects in genome-edited plants?
2. The comparative analysis is a pillar of the risk assessment of GM plants in the current EU regulation. What limitations or issues, if any, would you foresee for its applicability to plants developed through genome editing methods?
3. Exogenous/foreign DNA is a relatively clear concept for GM plants developed through transgenesis. Would you see any need to apply these terms to genome-edited plants, considering that any genome-edited plant containing also a transgene would be risk-assessed as standard GMO? How

would you define "exogenous DNA/foreign DNA" in the context of genome edited plants?

Question 1, related to off-target mutations, was already addressed during the discussion in agenda item 3.5. Regarding question 2, GijS A. Kleter (Netherlands) suggested to consider a tiered approach as regards the comparative analysis (substantial equivalence) for genome edited plants. Regarding question 3, Tamas Dalmay (GMO Panel) clarified that DNA encoding Cas9 and gRNA should be considered as foreign DNA, whereas the modification itself is not to be considered exogenous DNA. No further clarifications were asked.

Agenda item 4: Mandate on Synthetic biology

Nikoletta Papadopoulou (EFSA scientific officer) briefly summarized the content of the presentation given at the GMO open plenary (1st July 2020) on the outcome of the public consultation of the GMO Panel draft opinion on the "evaluation of existing guidelines for their adequacy for the molecular characterisation and environmental risk assessment (ERA) of genetically modified plants obtained through synthetic biology" in response to the EC mandate on synthetic biology (hereafter, SynBioP mandate). An update on the outcome of the parallel public consultation on the draft opinion of the EFSA Scientific Committee on microorganisms obtained through SynBio (hereafter, SynBioM) was provided. No further clarifications were asked from the GMO network members (agenda item 4.1).

Emmanuelle Pic (France) presented a summary of Anses comments on the SynBioP draft opinion, focusing on the molecular characterisation aspects. Since the meeting focused on GM plants, comments on the draft opinion for SynBioM were not discussed. A brief abstract of the presentation was provided by the expert and it is included below.

Presentation from Emmanuelle Pic (France) for agenda item 4.2: The main comments raised by Anses regarded the limits of the existing risk assessment methodologies to evaluate SynBioP and the issue of the off-target effects. Concerning the current risk assessment methodologies, Anses agreed with the fact that they will need to be revisited at regular intervals and improved when necessary, but expressed concerns regarding the possibility to achieve this in the context of rapidly evolving techniques. Anses also stressed the increasing challenges associated with the analysis of the expression levels of the newly expressed proteins, the study of the interactions (potential additive, synergistic, and antagonistic effects) and the risk assessment of each "event" before they are stacked. Regarding the off-target effects, Anses considered that this question was set aside too quickly, for the same reasons as mentioned before in the frame of the consultation on the draft scientific opinion on genome editing (agenda item 3.2). Anses also expressed some editorial comments, regarding the information provided about the documents used as reference documents and clarifications about what was done by the contractor and by the working group respectively.

Tamas Dalmay (EFSA GMO panel member and SynBio Plant ERA WG member) commented on the potential challenge of analysing a large number of newly expressed proteins (e.g. 100-200 modified or newly introduced proteins) in applications of SynBioP and confirmed that the GMO Panel will consider updated methodology if necessary or on a "case-by-case" basis. He raised also the issues of the insertion of multiple genes with a single transformation event and whether to consider these events as single or stacked as currently defined by the

regulation. Tamas Dalmay clarified that the GMO Panel was not requested in the frame of the SynbioP mandate to define what an event is within the Synbio developments. A representative of the European Commission confirmed that the discussion and additional clarifications raised in the GMO Network meeting will be taken note of.

On a request for clarification by the representative of the European Commission, Emmanuelle Pic (France) explained that Anses wondered whether the number of genes introduced in a SynBioP should be limited to a defined threshold as a consequence of the possible inadequacy of the current risk assessment methodologies for the evaluation of SynbioPs with numerous changes/"events".

Adinda De Schrijver (Belgium) stated that the current document lacks an extended "*outlook"* on how future 'true' Synbio developments could be assessed. In the future, risk assessment could become an integral part of the innovation process by implementing new concepts like "safe by design" approaches. It was suggested that such novel approaches for the risk assessment of potential SynbioP are considered in the document. In this regard, Boet Glandorf (Netherlands) commented that this approach is already included in the parallel draft opinion on SynBioM and highlighted the fact that SynbioM is a fast advancing field. Should the "safe by design" concept be considered relevant also for SynbioP, this could also be considered in the SynbioP opinion.

Nikoletta Papadopoulou (EFSA scientific officer) presented some open questions for discussion shared with the GMO network members prior to the meeting and explained the underlying rationale for extracting them from the public consultation (agenda item 4.4). The following questions were tabled for discussion:

1. For the molecular characterisation of GM plants the levels of all newly expressed proteins are analysed and assessed in relevant conditions and plant tissues. In case of SynBio plants where a high number of genes has been altered, including full metabolic networks, should protein expression for risk assessment be conducted differently, e.g. for selected relevant proteins? In that case, what criteria should be considered for making a selection of relevant proteins?
2. SynBio approaches may lead to numerous changes in the agronomic/phenotypic and compositional characteristics of the GM plant, that might challenge the comparative safety assessment as currently prescribed by EFSA (2010, 2011). Do you think that the current approach suffices, and if not, what changes should be considered, and why?
3. NTO assessment may need to be addressed differently for SynBio plants than currently done. In particular, it may no longer be able to test every single trait/protein for its toxicity. Discuss on whether NTO testing with GM plant tissue instead of isolated proteins should be considered.
4. Performing risk assessment of all single SynBio GM plant events before assessing a stack containing these single events may be challenging when assessing complex traits in GMPs obtained through SynBio. What approach would you propose for the assessment of such cases?
5. Finding a suitable comparator with a genetic background as close as the SynBio GM plants may entail challenges in future SynBio cases. Please provide your considerations on the concept of comparator for SynBio GM plants.

Regarding question 1 on the potential criteria for selecting the most relevant NEPs to risk assess SynBioP applications, Kleter Gijs (Netherlands) suggested to adopt similar approaches as used for Novel foods risk assessment where many different new proteins can be present or to consider the relevance of the final protein that will be produced by the SynbioP. Boet Glandorf (Netherlands) suggested to take into consideration only the final protein (the trait), as most important for risk assessment, an example being the case study with the Vitamin B pathway; the outcome of this pathway (Vitamin B production) could also be the target of the comparative approach. Regarding question 2, Emmanuelle Pic (France) considered it more relevant in the context of food & feed safety assessment, an area of the risk assessment of SynbioP that will be addressed in the next work packages of the SynBio mandate. No comments were received on question 3. Regarding questions 4 and 5, Boet Glandorf (Netherlands) suggested to consider a higher degree of flexibility on the assessment of singles and stacksand on the selection of a suitable comparator. In particular, she suggested to introduce more flexibility regarding the "single first" approach in SynBio applications if all relevant information to assess a Synbio "stack" is available. Furthermore, the selection of comparators for a complex SynBio trait should not be limited to only those with the same genetic background but should also consider other comparators with similar traits. As a general comment, more flexibility and a "case-by-case" approach was proposed.

Hanspeter Naegeli (Chair of the EFSA GMO Panel) pointed out that there were many comments in the public consultation beyond the scope of this mandate. In addition, he concluded that there is always a need to reflect and find a consensus in order to protect the consumer and the environment, keeping always in mind that not "what is theoretically possible" should be done but "what are the real risks" for the safety assessment should guide the risk assessment requirements.

Agenda item 5: Mandate on gene drive

Yann Devos (EFSA scientific officer) briefly summarised the content of the presentation given at the open GMO Panel plenary meeting (1 July 2020) on the outcomes of the public consultation on the draft GMO Panel scientific opinion on the adequacy and sufficiency of existing EFSA guidelines for the molecular characterisation (MC), environmental risk assessment (ERA) and post-market environmental monitoring (PMEM) of gene drive modified insects (GDMIs). No further clarifications were asked from GMO network members (agenda item 5.1).

Andrea Scheepers (Germany) and Wolfram Reichenbecher (Germany) presented a summary of their comments on the draft scientific opinion. A brief abstract of each presentation is given below:

Presentation by Andrea Scheepers (Germany) for agenda item 5.2: Andrea Scheepers from the German Federal Office of Consumer Protection and Food Safety presented some comments with regard to the EFSA draft scientific opinion on GDMIs. According to this, the considerations/requirements contained in the existing EFSA Guidance Documents (EFSA, 2012 and 2013) are considered to be either adequate or at least broadly adequate for the risk assessment (RA) of the presently considered GDMIs. In agreement with EFSA, the strategies for the ERA of genetically modified animals given in Section 2 of EFSA (2013) are considered to be adequate for the GDMIs under consideration. In this regard, the clear confirmation of the case-by-case approach in RA is welcomed. Regarding MC as well as the assessment of persistence and invasiveness, the presenter concurs

that an amendment/adaption of the existing guidance may be beneficial to better reflect GDMI characteristics (even if the already existing basic requirements and concepts are applicable to GDMIs). As the greater use of mathematical modelling will significantly benefit a sound RA of GDMIs, advice in this area is also welcome. Regarding the terminology of 'GMOs engineered with gene drives', it is strongly recommended to omit the use of the term "synthetically" as there is no definition or legal reference for it. Overall, the presenter agrees with the draft scientific opinion and thanks EFSA for the excellent work in preparing it. Nevertheless, some points should be adapted/reworked.

Presentation from Wolfram Reichenbecher (Germany) for agenda item 5.3: Wolfram Reichenbecher from the Federal Agency for Nature Conservation welcomed the EFSA mandate on synthetic gene drive insects and its relevance for the nevertheless broader Convention on Biological Diversity (CBD) process. EFSA's draft opinion extensively covers technical details and evaluates the efficacy for synthetic gene drives, but could include and scrutinize some topics in more detail, i.e. challenges of synthetic gene drives concerning the comparative approach, negative ecological effects with a focus on non-target organisms and the state of the art of ecological modelling.

Synthetic gene drives differ from non-drive GMO in their prerequisite to spread among and suppress or modify wild living populations in often natural or semi-natural environments inducing extreme spatial and temporal exposure. Those novelties trigger many open questions regarding (environmental) risk assessment of synthetic gene drives and more research is needed to enable i.e. ERA including baseline data and modelling methods (also performing sound uncertainty analysis) to evaluate ecological effects. Some general GMO ERA questions regarding e.g. specific effect threshold (limits of concern) also apply to synthetic gene drives. There is a clear need for further guidance to perform sound risk assessment of gene drives. In a wider context the profound changes by synthetic gene drives require a wider societal perspective and the development of a technology assessment approach.

Following the two presentations, some comments/questions were raised by the audience (agenda item 5.4). Gijs Kleter (Netherlands) asked further clarifications on the possible differences between GDMIs and invasive species, and on possible measures for confinement and remediation of GDMIs after release. Boet Glandorf (Netherlands) noted that the potential concerns highlighted in Wolfram Reichenbecher's presentation tend to cover all GDMOs, but were actually concerns for GDMI. She then questioned whether the same concerns are also applicable to GM insects and not only to GDMIs. Wolfram Reichenbecher was inclined to agree that the concerns highlighted are also applicable to GM insects. In addition, Leslie Firbank (GMO Panel member and chair of the Gene Drive ERA WG) clarified that several terms/definitions used in the draft scientific opinion would be further clarified in response to public comments received. He also highlighted that in line with the mandate's terms of reference, no guidance is intended to be produced; instead, the scientific opinion will identify the areas for which updated guidance would be needed for GDMIs.

Yann Devos (EFSA scientific officer) presented the questions for discussion already communicated to the GMO network members prior to the meeting, and explained the underlying rationale for posing them (agenda item 5.5). The following questions were tabled for discussion:

1. In which of their characteristics/dimensions, do engineered gene drives have similarities with and differ from current and emerging insect disease vector/pest control strategies (SIT, (fs)RIDL, IIT, PI, biological control)?
2. What experience has been gained from the application of current and emerging insect disease vector/pest control strategies (SIT, (fs)RIDL, IIT, PI, biological control) in terms of organism/product characterisation, environmental risk assessment, risk mitigation, post-release monitoring and biosafety research?
3. How can environmental risk assessment focus on quantifying risks to protection goals, and avoid the risks of open-ended data collection exercises?
4. What existing guidance on risk mitigation from current and emerging insect disease vector/pest control strategies could be useful for the risk mitigation of engineered gene drives?
5. Is post-market environmental monitoring (consisting of case-specific monitoring and general surveillance) as currently foreseen in the EU GMO legislation adequate and sufficient for gene drive modified insects? What experience can be gained from current and emerging insect disease vector/pest control strategies?

For questions 1 and 2, comments were made by the audience highlighting that insect disease vector/pest control strategies (e.g. *Wolbachia*-mediated IIT) are already applied in some areas and that experience is being gained; also that there are two publications that compared GDMIs to other insect control systems (e.g. Romeis et al., 2020 focusing on *Drosophila Suzukii* and the 2017 HCB Scientific opinion on pathogen transmitting mosquitoes).

Yann Devos (EFSA scientific officer) replied that the Gene Drive ERA WG is aware of such activities and that the relevant publications are taken into account in an attempt to address this point (comparison of GDMIs to other systems) as comprehensively as possible in the draft scientific opinion. Yann Devos also highlighted that some participants to the public consultation strongly opposed to the comparison of GDMIs to the existing insect control systems.

For question 3, Boet Glandorf (Netherlands) commented that the definition of operational protection goal is a transverse issue that is not specific to GDMIs. The lack of clarity on protection goals and decision-making criteria (such as what constitutes harm, limits or thresholds of concern, trigger values for action or acceptability of risk, judging the sufficiency of scientific knowledge and the extent to which uncertainty should be reduced for decision-making) can lead to an open-ended data collection exercise. It is therefore important to conduct an appropriate problem formulation exercise in order to clearly define the areas of risk/harm and define the limits of concern to avoid an open-ended data collection exercise. EC clarified that the issue of defining protection goals is horizontal.

For question 4, comments were made by the audience indicating that the PMEM as currently foreseen under relevant EU legislation can be considered adequate and sufficient provided that it is performed properly. Moreover, it was mentioned that the issue of how to best perform general surveillance is not evident for national risk assessment bodies due to the lack of a hypothesis-driven approach. The potential usefulness of national data gathering networks was highlighted, but with significant practical limitations such as access to data, lack of harmonised

methodology for data collection and the fact that not every MS has relevant networks.

For question 5, EFSA highlighted that there are now proposals by experts in the field to employ a phased testing approach where self-limiting GDMIs are released first before embarking on releasing self-sustaining GDMIs to gain experience and information that can feed into risk assessment. Gijs A. Kleter (Netherlands) commented on the possibility of international harmonisation for RA of GDMIs. EFSA clarified that its advice is expected to support the EU in its work under the Convention on Biological Diversity and the Cartagena Protocol on Biosafety, where the need for further RA guidance on engineered gene drives or not is under discussion. In addition, EC informed the GMO network members on the next steps as regards the EC's plan of communication/action at the global level (e.g. Cartagena protocol meeting).

5. Conclusions

The Chair summarised the actions to be taken after the meeting. The chair reminded that draft minutes will be circulated to the GMO members to provide feedback before publication on the 24th July. The chair asked all presenters to kindly provide an abstract of their presentations given during the meeting. The establishment of a platform to exchange information/ideas between members of the network was suggested to improve communication; technical possibilities will be explored by EFSA, taking into account the availability of new communication platforms. The chair also reminded that the period covered by the current GMO network mandate is at its end and a new mandate should be drafted with new terms of reference to cover the period 2021-2023. The GMO network will be informed as appropriate.

The Chair thanked the GMO Network experts for their active participation and the fruitful discussion, the speakers for the interesting and concise presentations, the GMO Panel members for contributing to the scientific exchange, and EFSA staff for organising and scientifically contributing to the meeting.

6. Closure of the meeting

The meeting was closed at 13.00.