SCIENTIFIC PANEL ON
GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 138th MEETING

Held on 1-2 July 2020, TELE/WEB

(Agreed on 27 July 2020)

Participants

Panel Members:

European Commission and/or Member States representatives:
Ilaria Ciabatti, Béatrice Marquez-Garrido and Alexandre Huchelmann (DG SANTE)

EFSA:
GMO Unit: Fernando Álvarez, Michele Ardizzone, Maeve Cushen, Giacomo De Sanctis, Yann Devos, Antonio Fernández Dumont, Silvia Federici, Andrea Gennaro, José Ángel Gomez Ruiz, Dafni Maria Kagkli, Anna Lanzoni, Sylvie Mestdagh, Franco Maria Neri, Lorenz Oberkofler, Konstantinos Paraskevopoulos, Nikoletta Papadopoulou, Tommaso Raffaello, Riccardo Vriz and Elisabeth Waigmann

Other Units: none

Observers: Apanasets Oksana (BASF), Achterberg Franziska (Greenpeace European Unit), Agapito-Tenfen Sarah (GenØk Centre for Biosafety), Ålander Johan (Swedish Food Agency), Alcalde Esteban (Syngenta), Arnich Nathalie (ANSES), Atanassova Ana (BASF), Batic Martin (Independent Researcher), Beech Camilla (CAMBEA CONSULTING LTD), Benevenuto Rafael (Federal University of Santa Catarina), Bertho Lieselot (Bayer CropScience), Bovers Marjan (COGEM), Bücking Elisabeth (retired), Burt Austin (Imperial College), Cagnetti Alessia (PoloGGB), Delzenne Pascale (Bayer), Dolezel Marion (Environment Agency Austria), Duressa Tewodros (Bayer Crop Science), Eckerstorfer Michael (Environment Agency Austria), Emmerig Hedwig (Green Group

1 As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf
The agenda was presented.

The Head of the GMO Panel warmly welcomed the observers who will follow the discussions through web-streaming. Members from the GMO Panel and the GMO Unit briefly introduced themselves through a tour de table.

The Head of the GMO Unit presented the guidelines for observers. The GMO Panel coordinator presented the instructions for a successful online meeting.

The agenda was adopted without changes.
4. Declarations of Interest of Panel members

In accordance with EFSA’s Policy on Independence\(^2\) and the Decision of the Executive Director on Competing Interest Management\(^3\), EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

5. Report on written procedures since the 137\(^{th}\) GMO Plenary meeting

The minutes of the 137\(^{th}\) Plenary meeting were adopted by written procedure on 16 June 2020 and published on 18 June 2020.

6. Scientific topic(s) for discussion

5.1 Scientific opinion on plants developed using type 1 and type 2 Site-Directed Nuclease and Oligonucleotide Directed Mutagenesis (\textit{EFSA-Q-2019-00297})

The scientific officer of the GMO Unit in charge reminded the GMO Panel about the background of this mandate from the European Commission (hereafter mentioned as ‘EC’). The EC tasked EFSA to advise whether the assessment methodology described in the 2012 scientific opinion of the GMO Panel addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function\(^4\), may be applicable, in whole or in part, to plants developed with type 1 and type 2 Site-Directed Nucleases and with oligonucleotide directed mutagenesis. If the answer is yes, EFSA is requested to advise whether the conclusions of the 2012 scientific opinion are valid, in whole or in part, to plants developed with type 1 and type 2 Site-Directed Nucleases and with oligonucleotide directed mutagenesis.

The draft opinion on SDN-1 and -2 and ODM was open to a consultation of the public (15 April to 5 June 2020). More than 300 comments were received from 51 stakeholders (e.g. NGOs, national competent authorities, industry, research institutes and universities). The scientific officer of the GMO Unit presented an overview of the comments that were classified as per their nature and relevance. The comments are currently reviewed by the Working Group of the GMO Panel on molecular characterization (\textit{EFSA website}) with particular emphasis on the comments related to e.g. off-target mutations, comparison between SDN/ODM and conventional breeding, multiplexing approach, use of comparative approach. Over summer the aforementioned Working Group will further digest the comments and revise the text of the draft opinion accordingly.

The adoption of the scientific opinion is expected by October 2020. Subsequently the adopted output together with a technical report on the public consultation will be made available online.

\(^4\) The scientific opinion is available at: https://www.efsa.europa.eu/en/efsajournal/pub/2943
5.2 Synthetic biology developments in plants, environmental risk assessment aspects (ERA) (EFSA-Q-2018-01000)

The scientific officer of the GMO Unit in charge introduced the overall concept and definition of synthetic biology as well as the terms of reference of the mandate received from the EC. The EC tasked EFSA to issue scientific opinions on synthetic biology developments in plants (for agri-food uses) to inform the EU position in international negotiations for synthetic biology (e.g. Convention on Biological Diversity). EFSA and its GMO Panel shaped their work considering agri/food/feed products about to enter the EU market over the next decade. EFSA established two multidisciplinary ad hoc Working Groups (WGs) to address the terms of reference: one focusing on microorganisms within the remit of the EFSA Scientific Committee and the other addressing plants falling under the GMO Panel (EFSA website).

The current scientific opinion covers GM plants and the risk assessment aspects for their molecular characterization and the environmental risk assessment for products deliberately released into the environment. In response to the mandate of the EC, the existing guidance documents concerning molecular characterisation, and environmental risk assessment of GM plants were evaluated for their adequacy.

The Scientific officer of the GMO Unit first explained the characteristics of Synthetic Biology as a toolkit to engineer modified organisms. She also mentioned that the draft opinion on Synthetic biology developments in plants was open to a consultation of the public (31 March till 4 June 2020). More than 200 comments were received from 45 stakeholders (e.g. NGOs, national competent authorities, industry, research institutes and universities). She presented an overview of the comments and further highlighted specific categories of comments, e.g.

- General comments (e.g. definition, scope, selection of case studies),
- Molecular characterization (e.g. off-target effects, single vs stacked event),
- Environmental risk assessment (e.g. choice of comparator, comparative safety evaluation, impact on non-target organisms).

The aforementioned ad hoc Working Group on plants is currently processing the comments and will revise the text of the opinion accordingly.

The adoption of the scientific opinion is expected by end 2020. Subsequently the adopted output together with a technical report on the public consultation will be made available online.

The Head of the GMO Unit pointed out the partial overlap between both mandates, Synthetic Biology and Site-Directed Nuclease and Oligonucleotide Directed Mutagenesis. She re-assured all participants that both Working Groups work in close contact for sake of consistency.

5.3 EFSA opinion on genetically modified organisms engineered with gene drives (gene drive modified organisms) and their implications for risk assessment methodologies (EFSA-Q-2018-00619)

The scientific officer of the GMO Unit in charge introduced (1) the background of the mandate from the EC, (2) the outcome of the public consultation and (3) the next steps:

1) The EC mandated EFSA to deliver a scientific opinion on gene drive modified organisms and their implications for risk assessment methodologies. According to the mandate specifications, EFSA was requested to identify potential risks in terms of impact on human and animal health and the environment that gene drive modified organisms could pose, including potential novel hazards of gene drive modified organisms, considering relevant comparators, where appropriate; to determine whether the existing guidelines for risk assessment are adequate
and sufficient for gene drive modified organisms or whether there is a need for updated guidance. In cases where a need for an updated guidance is found, EFSA was requested to identify the specific areas where such updated guidance is needed. Under the present mandate, EFSA is not requested to develop guidelines for the risk assessment of gene drive modified organism. EFSA is also requested to provide technical and scientific expertise on risk assessment of gene drive modified organisms to support the EU in the work under the Convention on Biological Diversity and the Cartagena Protocol on Biosafety. EFSA established an ad hoc WG to address this mandate (EFSA website). On 15 May 2019, EFSA also organized a Workshop on the problem formulation for the environmental risk assessment of gene drive modified insects to feed the discussions and contribute to the final output. EFSA met stakeholders and EU Member States to discuss plausible environmental risks associated with the release of gene drive modified insects into the environment. Comments raised at the Workshop were valuable inputs that contribute to the development of the draft scientific opinion.

2) The draft opinion was launched for public consultation (17 February till 24 April 2020). More than 1000 comments were received from 36 contributors (e.g. EU Member states, overseas agencies, NGOs, industry). Pending the technical report on public consultation addressing all comments received, the scientific officer of the GMO Unit in charge reported on most relevant and recurrent comments clustered by nature and relevance, e.g. terminology, remit & scope, composition of WG and EFSA independence policy, consultations, explaining engineered gene drives, potential novel hazards/risks. He provided insights on how the ad hoc Working Group plans to address the comments falling within the scope of the mandate. In this respect he drew the attention of the participants to the challenge that the ad hoc Working Group faces, namely to take into consideration diverging opinions on the gene drive concept applied to insects. The ad hoc Working Group will pay extra attention in reflecting these opposite views in the final opinion.

3) The ad hoc Working Group will revise and restructure the draft opinion in the light of the comments received. The adoption of the scientific opinion is expected by end 2020. Subsequently the adopted output together with a technical report on the public consultation will be made available online.

5.4 Application for renewal of the authorisation for continued marketing of genetically modified oilseed rape GT73 for feed containing or consisting of genetically modified GT73 oilseed rape and products other than food and feed containing or consisting of genetically modified oilseed rape GT73, submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-RX-002) (EFSA-Q-2016-00478)

Oilseed rape GT73 was developed to be tolerant to glyphosate-based herbicides, conferred by the expression of the CP4 EPSPS and GOXv247 proteins. Application EFSA-GMO-RX-002 was submitted for the renewal of the authorization for feed containing or consisting of oilseed rape GT73 and other products containing or consisting of oilseed rape GT73 (with the exception of cultivation) that were authorized under Directive 2001/18/EC.

Following the submission of application EFSA-GMO-RX-002- under Regulation (EC) No 1829/2003 from Monsanto Company, the GMO Panel was asked to conduct a thorough evaluation of the data submitted in the context of application EFSA-GMO-RX-002. In delivering its scientific opinion, the GMO

Panel also took into account additional information provided by the applicant, scientific comments submitted by the Member States and relevant scientific publications. The data received in the context of the renewal application contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search, updated bioinformatics analyses, and additional studies performed by or on behalf of the applicant. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application.

Under the assumption that the DNA sequence of the event in oilseed rape GT73 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-002 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on oilseed rape GT73 (EFSA, 2004).

During the meeting, the GMO Panel scrutinized and revised the draft text, where appropriate. The GMO Panel subsequently adopted the opinion, which will be published on the EFSA website and in the EFSA Journal.

5.5 Mandate to EFSA to complement its original scientific opinion on oilseed rape Ms8 x Rf3 x GT73, including the sub-combinations in scope of the application EFSA-GMO-NL-2009-75 (EFSA-Q-2018-00990)

The scientific officer of the GMO Unit in charge introduced the background of the mandate from the EC. The GMO Panel previously assessed oilseed rape Ms8 x Rf3 x GT73 and its sub-combinations Ms8 x GT73 and Rf3 x GT73 according to the scope of application EFSA-GMO-NL-2009-75. At that time, owing to missing information, the GMO Panel was not in the position to complete the safety assessment of products rich in protein, such as rapeseed protein isolates or products of this nature in animal feeding (link to initial opinion).

Subsequently the applicant provided a novel 28-day toxicity study in mice with the glyphosate oxidoreductase (GOXv247) protein to supplement the initial scientific opinion of the GMO Panel. The 28-day toxicity study on E. coli- produced GOXv247 protein did not show adverse effects in mice under the testing conditions. In the light of the assessment of the novel 28-day toxicity study in mice, the GMO Panel followed a weight of evidence approach to conclude that food and feed containing, consisting and produced from oilseed rape Ms8 x Rf3 x GT73 and its sub-combinations Ms8 x GT73 and Rf3 x GT73, are as safe as its conventional counterpart, according to the scope of application EFSA-GMO-NL-2009-75.

During the meeting, the GMO Panel scrutinized and revised the draft text, where appropriate. The GMO Panel subsequently adopted the opinion, which will be published on the EFSA website and in the EFSA Journal.

5.6 Mandate to EFSA to assess additional information related to the application for authorisation of food and feed containing, consisting of and produced from genetically modified soybean MON 87796 x MON 89788 (EFSA-GMO-NL-2010-85) (EFSA-Q-2019-00329)

The scientific officer of the GMO Unit in charge introduced the background of the mandate from the EC. The GMO Panel previously assessed the nutritionally altered soybean MON 87769 x MON 89788 according to the scope of application EFSA-GMO-NL-2010-85; this two-event stack soybean was produced by conventional crossing of the soybean lines MON 87769 and MON 89788, combining the production of stearidonic acid (SDA) and γ-linolenic acid (GLA), and the tolerance to glyphosate-based
herbicides. At that time, owing to missing information to conclude on the human nutritional assessment of the refined bleached deodorised (RBD) oil from soybean MON 87769 × MON 89788, the GMO Panel was not in the position to complete the safety assessment (link to initial opinion).

With the EC mandate on May 2019, the GMO Panel received additional information consisting of the human nutritional assessment of RBD oil. During its evaluation, the GMO Panel posed further questions to the applicant. The scientific officer of the GMO Unit in charge reminded participants about the principles of the nutritional assessment, presented the strategy followed during the assessment, and the outline of the draft opinion pending evaluation of additional data recently received from the applicant. The Working Group on Food/Feed evaluation (EFSA website) will assess the additional dataset and may either pose further questions or draft the supplementary opinion accordingly. Depending on the situation, the draft opinion may be proposed to the GMO Panel for possible adoption by written procedure.

Post-meeting note: Following the assessment of the additional information received on 30 June, further questions are needed to be asked to the applicant before the risk assessment can be finalised.

6. New Mandates


Since the last meeting of the GMO Panel, EFSA received the following:

- application EFSA-GMO-IE-2020-166: dried killed GM bacterial biomass from Methylobacterium extorquens KB203 for use in feed (EFSA-Q-2020-00397);
- application EFSA-GMO-RX-018: glyphosate-tolerant cotton GHB614 (EFSA-Q-2020-00420)

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

No new mandate was received.

6.3. Other Requests and Mandates

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

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

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

The Chair of the GMO Panel reported on discussions at the last Scientific Committee meeting, on new mandates and ongoing EFSA activities.
7.2. EFSA including its Working Groups/ Task Forces

Establishment of a Working Group of the EFSA GMO Panel on allergenicity: this activity is a continuation of the previous activities of the GMO Panel on the topic. The Chair of the GMO Panel appointed Javier Moreno as Working Group Chair. As outlined in the mandate, the GMO Panel will task the Working Group to produce two deliverables: (1) a Statement on the usefulness of *in vitro* protein digestion in risk assessment; and (2) a Scientific Opinion providing recommendations for future developments in the field of allergenicity assessment. The Working Group will include experts with competencies on *in vitro* protein digestibility, food allergy and risk assessment. Continuity with previous activities related to allergenicity will be ensured by enrolling relevant experts from the former ad hoc ‘Allergenicity’ Working Group. Furthermore, EFSA will continue fostering stakeholders’ engagement.

7.3. European Commission

The representative of the EC provided feedback on ongoing activities (e.g. study on new genomic techniques to Council, new mandate to EFSA referred to in item 6.3).

8. Any other business

Scientific officers of the GMO Unit updated the GMO Panel on the recent developments with application EFSA-GMO-NL-2014-122. The scientific opinion adopted by the GMO Panel was ‘suspended’ owing to the outcome of an audit of the test facility that pointed to a lack of compliance with GLP standards of one of the 90-day studies with a single event. Following further investigation of the auditors including discussions with the facility where the study was conducted and the applicant, EFSA recently received an amended report of the study at stake demonstrating only minor deviations to GLP principles. This will lead to the republication of the scientific opinion previously suspended. The scientific officer in charge made clear that the revised report does not impact on the conclusions of the risk assessment for application EFSA-GMO-NL-2014-122.

9. Questions from and answers to Observers

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

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<th>QUESTIONS</th>
<th>ANSWERS</th>
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<td>According to the literature and discussions, the true and conceivable potential and promise of SDN-1 and SDN-2 interventions lie with multiplexing rather than single changes. Could EFSA please explain/elaborate why multiplexing SDN interventions were not considered? How does that impact the opinion’s coverage and validity?</td>
<td>This question was reiterated during the meeting and addressed under the Q&amp;A session of the relevant agenda item (please see table below).</td>
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On 28 May 2020 there are no documents posted except general agenda. I will likely have some questions regarding how you propose for the users of enzymatically driven mutations to evaluate possible risks of food allergy, or what the requirements will be. It seems often hypothetical questions end up dominating evaluation processes, for instance, questions of adjuvanticity a few years ago. Or questions about evaluating possible changes in the endogenous allergen expression of a GM event. With mutation analysis, or CRISPR Cas 9 etc., that can be a question, yet there are not good standards of what the natural variation is in non-GM varieties of similar plant varieties. Or whether there is evidence of risk. What levels of change is important.

The comment related to the enzymatically driven mutation aspect will be considered during the discussions with the Working Group.

In relation to your comments on the allergenicity assessment, the GMO Panel performs a safety assessment following its guidance documents and using a weight-of-evidence approach, taking into account all the information obtained on the newly expressed protein (EFSA GMO Panel, 2011; Regulation (EU) No 503/2013). The general principles of such approach are in line with international guidelines (Codex Alimentarius 2009). In relation to the second comment, adjuvanticity of newly expressed proteins and in particular of specific Cry proteins has been suggested when applied at relatively high doses in animal studies. Adjuvanticity is an aspect considered in scientific opinions of the GMO Panel. Furthermore, in 2018, EFSA published a comprehensive technical report on the topic that focused on the adjuvant capacity of Cry1Ac protein and its relevance in the context of GM plants assessed by the GMO Panel (EFSA, 2018). This assessment was an answer to concerns on the relevance of potential adjuvanticity of Cry proteins obtained from the literature. Finally, and in relation to your comment on endogenous allergens, natural variation is still considered a key initial element to take into consideration for the assessment of such endpoints. This is in line with Codex Alimentarius 2009. Furthermore, a vast amount of experience and data have been collected in the last years providing a favourable frame for the development of a proper database that can be used to contextualise the variation of endogenous allergens.

Given that gene drive engineered organisms are currently non-recallable and may pose severe threats to biodiversity or human health: How will EFSA make sure that there will be a prior political decision (European Parliament / EU Council of Ministers) before any authorization to begin field trials or other environmental releases of gene drive engineered organisms for risk assessment

Out of EFSA’s remit

EC reply:

- Gene drive engineered organisms are GM organisms as defined in the EU legislation. Their release into the environment is regulated in the EU under Directive 2001/18/EC of the European Parliament and the Council. In this Directive the legislators (the European Parliament and the Council) set the requirements and authorisation procedures for the deliberate release of GMOs into the environment.

- As provided for by the EU regulatory framework, the co-legislators (Council of Ministers and European Parliament) are not involved in the national decisions on releases for purpose other than placing

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8 [http://www.fao.org/3/a-a1554e.pdf](http://www.fao.org/3/a-a1554e.pdf)
on the market. Such releases fall under Part B of the Directive and must be approved at Member State level following an environmental risk assessment by the national competent authorities. Nevertheless, the other MS and the EC may raise observations and the relevant MS has to consider these observations. According to Article 11 of the Directive, the EC has set up a website, where information on experimental releases of GMOs are made available (https://gmoinfo.jrc.ec.europa.eu/). In this site you can find:

- summaries of all notifications under Part B of the Directive;
- final Decisions taken by the MS and
- results of the release in respect to any risks for human health and the environment

When it comes to releases for placing on the market, any Member State may raise objection and the authorisation decision is taken according to comitology procedures.

| What is the current understanding of the safety of GMO products as the levels of herbicides within GE food are increased and where does the consumer keep up with the knowledge to understand those increases when they are discussed? Has there been additional information released on the toxicity of Glyphosate and other herbicides to date and where is that information available to the public? | Most of GM herbicide-tolerant crops assessed by the GMO Panel are for import and processing within the European Union (not authorized for cultivation).

Regulation (EU) No 503/2013 requires the exposure of test material to the intended herbicide(s). The comparative assessment is therefore conducted accordingly.

Regarding the question on increased herbicide levels: in the EU, the presence and amount of different herbicides in foods is monitored by the Member States. The results of these monitoring activities are compiled and published annually by EFSA; they can serve as an information source for the situation in the EU. This spring, the "2018 European Union report on pesticide residues in Food" has been published on EFSA’s webpage. Regarding the toxicity of glyphosate or other herbicides: in the EU system, herbicides authorisations have to be renewed every 10 years taking into account the newest scientific evidence. An outcome of this review is published by EFSA. For glyphosate the renewal period has been reduced to 5 years, hence the renewal dossier should be submitted soon.

Would the Panel be able to comment on the recent AHTEG report on a similar topic and that report’s diverging conclusion? | As any other relevant publication, the AHTEG report is being considered by EFSA and its GMO Panel for the revision and finalisation of the EFSA scientific opinion. In this respect, we can also clarify that EFSA contributed to the Open-Ended Online CBD Forum. One of the topics tabled for discussion from 20 January 2020 till 1 February 2020
Is there a concrete plan for a stand-alone Guidance document for the risk assessment of Genome editing appl., which follows up in detail the open issues identified in the current draft opinions relevant for gen ed. appl. of different complexity?

This question was reiterated during the meeting and addressed under the Q&A session of the relevant agenda item (please see table below).

Besides environmental risk assessment of synthetic biology applications, does the Panel expect that food & feed safety may also be addressed separately under a possible future mandate?

The request of the EC on Synthetic Biology covers GM plants, GM microorganisms and GM animals. It covers both ERA and Food and Feed Safety. Due to the complexity of the request, it was agreed that EFSA would start with MC and ERA aspects of GM plants and GM microorganisms. Further work will be decided on by taking into account the case studies identified, the current workload of EFSA in the area of biotech mandates, and the limitations posed by the COVID situation.

Could some details already be provided on the new mandate to review the safety of in-vitro mutagenesis techniques?

EFSA has received the mandate. The mandate and its terms of reference (ToR) are published in the Register of Questions. Completion date is September 2021, ToR include an analysis of the mechanism and mutation type that can be caused by in vitro/in vivo mutagenesis. Aim is to analyse whether or not a distinction between random in vitro and vivo mutagenesis is scientifically justified.

What experiences does the Panel have with the bioinformatics-supported assessment of potential celiac-disease-causing peptides present within newly expressed proteins? What strategy should be followed if positive hits are found? In a recent application, for example, the applicant provided arguments as to why particular hits would nonetheless not give rise to any concerns

The GMO Panel assesses the potential of newly expressed proteins to cause adverse effects, including celiac disease. In the latter case, the GMO Panel performs such assessments in line with its guidance document published in 2017[^10]. For more information, please note that several scientific opinions on applications containing a description of the assessment performed in relation to celiac disease have been recently published (e.g. EFSA GMO Panel, 2019a[^11],2019b[^12]). The specific partial matches identified in these two example applications did not raise concerns to the Panel.

Additional efforts are imperative on this topic as new findings show that proteins from origins other than cereals might display hazardous potential for individuals with celiac disease[^13].

We take this opportunity to raise a question on the scientific handling of application EFSA/GMO/BE/206/138 (MS11): We question the scientific relevance of assessing such a ‘hypothetical’ product not to be marketed. It raises scientific questions that would not have been an issue (e.g. on the compositional analysis) if the product to be placed on the market (MS11 x RF3) would have been handed in as an application. Further, the handling of this application is seen an example of a procedure leading to an unnecessary workload and a waste of time and money. We therefore wonder why not a more scientific approach was taken for the handling of this application.

| EFSA reply: Indeed, this application is out of the standard box because of the biological characteristics of the trait (male sterile). This has also been acknowledged by the GMO Panel who has presented conclusions for two different scenarios in its opinion on MS11, taking into account that MS11 is not intended to be placed on the market. Furthermore, due to the exceptional situation, EFSA has worked in parallel on the single application for MS11 and the stacked application MS11xRf3. |
|——|
| EC reply: The EC also acknowledged that it was a rather “unusual” application. Still the risk assessment has been done according to the legislation on GM food and feed and the EFSA guidance for the risk assessment of GM plants. |

My follow-up question on MS 11 would be for COM: Could a derogation be given for handing in a single application if a scientific reason can be given (e.g. that the risk assessment cannot be done according to the IR for the single event)?

| Article 5(2) of Commission Implementing Regulation (EU) No 503/2013 provides that, by way of derogation, an application may be submitted that does not satisfy all the requirements of Article 5(1) in very specific cases (referred to in Art. 5(2)(a) or 5(2)(b)) and the applicant has to submit reasoned justification for the derogation. |

Regarding the statement “off target effects in SDN- and ODM-based technologies is negligible compared to conventional breeding” and “the GMO panel considers that the analysis of potential off target effects would be of very limited value for the risk analysis”, how does this take into account the scientific literature confirming off target effects to be of paramount importance with regard to genome editing? See Agapito-Tenfen et al. (2018) Front. Plant. Sci. 9: 1874; Cotter et al. (2020); Eckerstorfer et al. (2019). Front. Bioeng. Biotechnol. 7: 31; Kawall (2019) Front. Plant Sci. 10, 525; Wolt et al. (2016) Plant Genome 9: 18; Zhu et al. (2017) Trends Plant Sci. 22: 38–5).

| These papers were considered during the development of the opinion. However, the Working Group also considered recent experimental data demonstrating that off-target mutations generated by SDN-based methods are of the same types and in significant lower number compared to mutations generated in conventional plant breeding including random mutagenesis. The text of the off-target section in the opinion will be improved accordingly. |
We appreciate the EFSA GMO Panel’s efforts to assess the applicability of existing guidance documents on emerging technologies such as Synthetic Biology, SDN-1, SDN-2 and ODM. Continuous efforts are ongoing to update existing EFSA guidance documents to the latest available scientific information. Similarly, other global regulatory agencies are amending and modernizing their regulations on genetically engineered organisms, such as the USDA APHIS. In light of the ongoing efforts and changes, we’d like to understand the EFSA GMO Panel’s view on how this momentum can be used to reflect on the more than two decades of experience with GMO risk assessment in the EU and whether existing data requirements are still applicable and appropriate today?

Certainly, experience and new developments are both drivers for updating Guidance Documents (GDs) or explanatory notes. When it comes to changes in the Regulation, this is in the hands of the EC and the Member States. We are in the situation that Commission Implementing Regulation (EU) No 503/2013, based largely on EFSA GDs, is very prescriptive with regard to data requirements. Hence it is more difficult to introduce horizontally applicable changes in the data requirements.

In the recent EFSA consultations (gene drives, synthetic biology and SDN1/2) that are taking place, as well as in the presentations of the 134th plenary meeting of the GMO Panel, EFSA highlights the application of a case-by-case approach to the risk assessment, since some of the requirements might not apply in all the cases. EuropaBio agrees that some requirements might not apply or might have to be adapted, and this is also the case for some GMO applications. We would like to understand how EFSA is ensuring the practical implementation of the case-by-case approach and seek confirmation that for data requirements not relevant for a particular product the derogation clause in Implementing Regulation 503/2013 can be applied.

EFSA reply: The case-by-case approach is indeed one of the principles in GMO Risk Assessment. It can be called upon if a certain data requirement is technically not feasible or scientifically not relevant. An example for implementation of these principles are data for GM plants with RNAi technology. In this case, several data requirements are not considered scientifically meaningful such as expression levels or toxicological studies with dsRNA or small RNAs. An important consideration in this respect is that the available set of data has to provide enough information to support a conclusion.

EC reply: For very specific cases, a reasoned justification for derogation can be submitted, at the time of the submission of the application, by applicant, in case a study specified in Implementing Regulation would not be submitted as part of the application, according to Article 5(2)(a) or 5(2)(b). The assessment of the reasoned justification will take place during the risk assessment performed by EFSA. As expressly set out in Article 5(3) of Implementing Regulation, EFSA is not prevented from requesting the applicant, where appropriate, to supplement the particulars accompanying the application.

Perspective in GMO in vitro testing

EFSA would need more insights to adequately address this comment. It is not clear whether the question touches upon the mandate on in vitro mutagenesis (if so, please see above), the inclusion of in vitro assays into the risk assessment of GMOs, or the detection of GMOs in vitro. The
latter is not in EFSA remit; the Joint Research Centre of the EC is responsible for developing the detection methodology.

From the safety perspective, in vitro testing is currently applied to several aspects in the assessment of GMOs by the GMO Panel. For example, the assessment of newly expressed proteins includes in vitro degradation studies to be carried out in all cases as a mandatory study. Furthermore, and on a case-by-case basis following the outcome of the bioinformatic analysis additional in vitro studies (e.g. IgE binding test, HLA-DQ binding assay) might be needed to further elucidate the capacity of the newly expressed proteins to trigger adverse effects. Finally, EFSA is further exploring the development of more robust in vitro approaches, a new Working Group will start soon on in vitro degradation studies and future procurements will investigate potential in vitro tests for the allergenicity and toxicity assessment.

In addition to the questions referred to above, observers could also pose questions during the meeting. Questions received (exact quote from web-streamers) and replies given by Panel member or GMO Unit staff are reported in the table below.

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<tr>
<th>AGENDA ITEMS</th>
<th>Questions from observers</th>
<th>EFSA/EC replies</th>
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<td>6.1</td>
<td>Is there a concrete plan for a stand-alone Guidance document for the risk assessment of Genome editing appl., which follows up in detail the open issues identified in the current draft opinions relevant for genome edited applications of different complexity?</td>
<td>This will depend on the final outcome of the opinion on SDN1,2 and ODM. EFSA will discuss a possible follow-up with the EC. EC confirmed that the need for further guidance will depend upon the EFSA response to the current mandate. The Head of the GMO Unit also mentioned a newly received mandate on new genomic techniques to be completed by end October 2020 (contemporaneously with SDN/ODM mandate).</td>
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<td>To what extent will the opinions, guidances, rulings, etc. from non-EU authorities be taken into account, such as the recently issued USDA ruling?</td>
<td>The Chair of the Molecular Characterization Working Group confirmed that staff and experts continue tracking the related discussions and decisions/rulings from all over the world. However,</td>
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from a legal perspective, there is no mutual recognition and, in terms of risk assessment guidance, one needs to follow the approach and requirements set at EU level.

According to the literature and discussions, the true and conceivable potential and promise of SDN-1 and SDN-2 interventions lie with multiplexing rather than single changes. Could the GMO panel please explain why multiplexing SDN interventions were not considered? How does that impact the opinion's coverage and validity?

It should be noted that multiplexing (pyramiding/stacking) could also be achieved by conventional breeding approaches. This point was extensively discussed with the Working group. Multiplexing SDN interventions are actually not excluded from the draft opinion on SDN1,2 and ODM. The considerations can be applied to both single changes and multiple changes introduced by SDN1,2 and ODM.

A member of the Molecular Characterization Working Group highlighted that multiple genomic changes are not new in breeding processes and older methods, like marker assisted selection (MAS) have already been applied to achieve it. Assessing multiplexing is not excluded in the considerations described in the SO and the case-by-case principle can be applied in cases of multiplexing too.

6.2 Did the ad-hoc WG members came across developments that would perhaps not fall within the remit but still be relevant as a new field or within the remit of other Panels? Examples: synthetic biochemistry and synthetic microbiomes?

From the horizon scanning, EFSA concluded that SynBio plants that may reach the market in a near future would not be derived from developments outside the remit. The situation differs for microorganisms where the horizon scan brought up many more advanced research projects.

Additional comment on Synbio documents (not a question): Notably, the documents refer to the possibility to incorporate "safe-by-design" concepts into the development of synbio organisms. This is just to note that within the OECD Working Groups on biotech safety, there is currently an ongoing discussion on a Dutch proposal to develop guidance for this concept applied to biotechnology.

EFSA thanks the observer for the comment.
I am curious about horizontal gene transfer (HGT) questions. What are the risks? What types of genes/proteins would be of concern? And what is evidence for HGT?

Follow-up question: My question in part is what types of genes would be of concern? If it cannot be defined, is it an interesting hypothetical question, but how can it be addressed?

A member of the Molecular Characterization Working Group highlighted that irrespective of the DNA sequence identity, a very important aspect inducing HGT is the selective advantage that a transgene might bring to an organism. For gene drive it is different because the GD module is designed to persist so additional considerations as regards the potential increase in probability for HGT to occur should be taken into account.

The EFSA explanatory note on HGT describes pre-requisites (e.g. sequence homology). Overall problem formulation is always key. The Molecular Characterization Working Group chair reiterated that the requirements for in silico analysis are laid down in the HGT technical note. The gene function and any known associated potential health risks (e.g. antibiotic resistance genes) are important factors for the risk assessment.

The expectation would be that we do not have too many examples of genes that would be of a clear safety concern.

Few questions related to the aforementioned question on HGT: (1) what is the pathway to hazard? (2) And why/when is an exposure assessment needed?

In the frame of new mandates for discussion, the absence of exogenous DNA inserted was discussed for the impact on specific data requirements such as HGT data. The case-by-case approach remains applicable.

Could you briefly comment on the proportion of responses that fell outside scope of the mandate?

For the time being, it is difficult to provide a precise number of comments falling outside the scope of the mandate. However this will be provided in the technical report on the public consultation.
This clearly focuses on GDMIs for which it is the intended and declared goal of the developer to introduce a gene drive. Vice versa, could we assess the possibility of any DNA modification to act as a gene drive or, more broadly, as a "selfish gene" (e.g. cytoplasmic male sterility)? For example, has the gene drive WG taken into account “biodefense” work done by the US department of Defence (DARPA), such as the Safe Genes program focusing on preventing and un-doing the spread of unwanted gene drives used as bioterrorism agents? Notably, it also considered the impacts of different types of gene drive such as self-limiting versus non-limiting ones, the effect of thresholds, etcetera.

Yes, the ad hoc Working Group on Gene Drive G is aware of this work.

In the draft opinion on GDMIs, enhanced dialogue between risk assessors, risk managers and stakeholders is advocated to clarify how ERA can address protection goals and define decision-making criteria for the ERA of gene drive modified insects. Since synthetic biology – as gene drive – can be considered as a new technology that will trigger questions from society, we wonder why this enhanced dialogue between stakeholders has not been included in the draft opinions on SynBio (and SDN-1 & 2)? Such an enhanced dialogue seems relevant for all of the new techniques discussed in the different draft opinions.

With GM plants there is already familiarity and history of use established; the case studies selected in the context of the SynBio opinion can be considered a continuum with the already existing GM plants. For gene drives in insects this is not the case; there is no familiarity or history of use for GM insects established yet. On top of this, gene drive is a novel characteristic.

I would like to ask a question here, in the context if our current ERA framework is applicable for the complex impact like GDOs. I am sorry I was not able to submit this question upfront
The mandate of the panel suggests, by using the reference documents EFSA 2012, 2013, to integrate the new techniques into existing frameworks of risk assessment or ERA respectively (with the possibility of their adaptation). The applicability of existing ERA frameworks to GDOs had been recognized in the GDO Draft opinion. However, the increasing complexity of the techniques and their interactions with the environment makes also the application of traditional ERA more complex. Fundamental new approaches that goes beyond “new hazards” might be required, or might be more applicable. Indications that this is shared by parts of the scientific community was already included in the appendix of the GDO draft opinion. The question is therefore: How can it be prevented that the mandate itself does not hinder an advancement of

We operate under a given legislation defining a frame. For the mandate on Gene Drive, problem formulation and flexibility in data requirements stand. We need to bear in mind different scenarios, some more plausible than others. Self-limiting scenarios are part of the picture as well as discussion on various tools such as modelling. Risk assessment can be tailored to protection goals that risk managers want to achieve.
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<th>Question</th>
<th>Answer</th>
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<td>ERA procedure beyond the traditionally conceived risk hypotheses? Would it have been possible within the mandate of the panel to communicate such a necessity? And if not, what procedure would allow this?</td>
<td>Yes, this is part of the draft opinion.</td>
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<td>Will a discussion of the significance of modelling in the assessment provided in the final opinion, as this might be a prominent tool in the ERA of GDMIs</td>
<td>Complexity in assessment is set against a certain basis and is comparative. Assessment can be complex depending on the case. The intention of the work is not to address specific cases, mosquitoes and agricultural pests are examples.</td>
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<td>From this insufficient Wiki assessment (<a href="https://en.wikipedia.org/wiki/Mosquito#Ecology">https://en.wikipedia.org/wiki/Mosquito#Ecology</a>), we would already hardly call the ecology of mosquitoes simple and the risk of spread from one strain to others low.</td>
<td>Risk/benefit analysis falls outside the EFSA remit and scope of the mandate but surely a fair point for risk managers.</td>
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<td>Can you discuss the impact of the COVID-19 pandemic on our assessment of risk/benefit, given how difficult it will be to distribute bed nets? Or any other new ideas that you are considering given what we have learned in the pandemic?</td>
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<td>6.5 Question 1 about GT73 renewal: The possible range of human food applications may have extended beyond canola oil since the initial (original) application as recent food innovations have made canola meal suitable for consumption as food ingredient. Is this taken into consideration?</td>
<td>The previous amount/type of data available was considered. The 28-day study provided is the only repeated dose toxicity study provided on this protein and added a substantial weight to the available evidence for concluding on the protein’s safety. On a broader context, it may be useful/informative to perform some data mining on all the available 28-day tox studies to assess what effects have been identified and assess the added value of such studies in the context of protein safety assessment.</td>
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<td>Question 2: Does the outcome of the 28-day study show that the previous assessment without in-vivo data would already have sufficed?</td>
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<td>My pre-meeting question to EFSA on 28 May 2020 was a request for detailed transparency of what EFSA is asking for in methods, and in risks related to Gene Editing, synthetic biology and Gene Drives.</td>
<td>EFSA performs its safety assessments according to its</td>
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<td>In my more than 20 years of GM safety assessment including being an observer at the CODEX 2003</td>
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guideline, managing the AllergenOnline.org (2005) and our embedded Celiac Database search system (2012) in the Food Allergy Research and Resource Program at the University of Nebraska since 2004, I have seen EFSA move multiple times from hypothetical questions of "interest" to specific protocols and demands to developers that have often not been based on scientific fact and findings.

For instance, insisting on increased pH for pepsin digestion assays, targeted serum IgE tests and animal models or predicting possible sensitization, and then possible adjuvanticity of recombinant proteins that are expressed at very low ppm in the food plant product. What is the proof of that being a risk?

For Horizontal gene transfer, when it seemed a clear potential risk, the question was whether an ARM (NPT II) might be transferred into soil microbes and make an ARM resistant "superbug". Kaare Nielsen in Kornelia Small's lab in Germany tried by testing HGT with Acinetobacter transformed with a gap-cut in the gene for kanamycin resistance. If the gap was 10 nucleotides long a huge amount of DNA from GM sugar beet cause complementation at a low rate. If the gap was 200 nucleotides, no "intact bacteria" were recovered. It was in the lab, and also in field conditions if I remember. Pretty convincing. What does it take to transfer DNA...microbe specific. That was a time when companies with enzyme production were composting their dead bacteria in the soil. (see Goldstein et al., 2005, J Applied Microbiology, 99:7-23).

As far as I know, there is no other data to demonstrate HGT possibilities in a realistic risk assessment. So how does EFSA want an evaluation? And are there examples of a 200 nucleotide piece of DNA from an organism, not a virus, being randomly incorporated into another microbe, fungi or plant?

By simple BLASTN to microbial genomes with the whole genome of a recombinant organism? Or are there sequences needed of homology? Or boarders?

Does that make sense? I had to do an evaluation for a company with a 62 kDa nucleotide insertion, against ALL microbial and archaea genomes known guidance document\(^{14}\) that are in line to international guidelines\(^{15}\), and ensuring that the highest standards possible are met. As science evolves, new developments are to be integrated into the risk assessment process, when relevant. Allergy is a continuously evolving field where the scientific community is taking great steps forward for a better understanding of the disease. In this context, EFSA published a guidance document 2017, describing in more detail the limitations and development needs of specific aspects of the allergenicity assessment. Furthermore, EFSA will continue to invest on additional development needs in this area with a great potential for further improvement.

The assessment of HGT is a recurrent topic discussed in previous Open Plenaries and with several meetings with stakeholders. EFSA is aware of Kaare Nielsen’s paper that actually shows that foreign DNA can be taken up by bacteria under certain laboratory conditions. If the DNA gets fixed in the genome or not depends on selective advantages conferred by the piece of DNA. ARM genes provide an obvious advantage, but also other genes can provide selective advantage.

It is important to remind that the assessment of HGT is a requirement laid down in Directive 2001/18 and of Regulation 503/2013. In Regulation 503/2013 the applicant is requested to assess the probability of HGT. EFSA decided to move from a narrative description of the likelihood of


\(^{15}\) http://www.fao.org/3/a-a1554e.pdf
at the time. That was ~ 2 years ago. How can one evaluate possible transfer and risks? That is not at all clear. Can EFSA please focus on realistic expectations and risks rather than that general statement?

Celiac disease. We (FARRP) have a database of native and deamidated peptides that have been published with positive results showing they stimulate T cells or induce toxic reactions from cells of celiac patient, all are 9 AA or longer. But EFSA has taken a hypothetical approach with a 4 amino acid core with 2 variable positions as a very reputable, but in this case, hypothetical demonstration by a celiac expert suggests that microbial proteins fitting those requirements “may” be the stimulus of initiation of celiac. (We have tried to publish our database in two journals, but they want shorter papers and I need to revise and submit to a third). Questions of changes in endogenous allergens for a species, have been asked often for GM crops. And what is the measure of too much difference? I am an expert on food allergy. There is no data to support what should be measured and how much change would be important, as we do not have data of variation across natural organisms of the same species grown under different conditions. It would clearly be species specific. So will EFSA ask for a comparison of “known” allergens of all allergens in a gene edited species? I am the Chair of the WHO/IUIS allergen nomenclature database and the manager of AllergenOnline. Some “allergenic species” such as house dust mite, have 30 “allergenic proteins”, yet 3 are the dominant allergens. What will be studied and how? Simply IgE binding? As a fellow in the American Academy of Allergy, Asthma and Immunology and a member of the European Academy of Allergy, I can tell you that we do not have good measures of potency except clinical trials, or at least, basophil histamine release. And that individuals with allergy have very different sensitivities. So, what is EFSA proposing? (Goodman et al. 2016, Mol Nutr Food Res 60(5):1183-1198); Pomes et al., Mol Immunol 100:3-13).

In relation to your comments on celiac disease, EFSA is aware of the FARRP database, and other databases containing sequences involved in celiac disease. Similarly, several databases are also available for IgE mediated allergy related sequences. Differences in databases can lead to misunderstandings and different risk assessment outcomes, and a manuscript on this aspect has been recently published. In 2017, EFSA published a guidance, providing detailed guidelines on how to perform the safety assessment of novel proteins in relation to their capacity to cause celiac disease. During the last years, EFSA has gained experience in the safety assessment of celiac disease and published opinions (e.g. EFSA GMO Panel, 2019a ,2019b). So far, no issues have been identified in the safety assessment of these proteins. The commenter refers to the relevance of the 4 amino acid motif described in the 2017

recombination to a more standardized analysis based on BLAST as extensively described in the technical report EFSA published (EFSA et al. 2017). It remains clear that the similarity search is only a part of the HGT assessment, since as discussed yesterday, in addition to the consideration for the likelihood of recombination, the risk assessment also includes the identification of potential hazards caused by the transfer of the genetic elements of bacterial origin from the GM plants to environmental bacteria.
EFSA wishes to reinforce the view that this element is used to focus the assessment on those sequences that might need particular attention and not because they are hazardous per se, as the hazard continues to be the 9-amino acid core of the epitope. Celiac disease in risk assessment has been discussed in different fora and congresses, and EFSA will continue to promote these constructive discussions in the future. As soon as the papers of the commenter will be publicly available, EFSA is committed to assessing those and to consider their relevance in the risk assessment, as for any other scientific information.

In relation to endogenous allergens, EFSA also performs such assessment in line with its guidance document and international documents. The lack of data has been used in many occasions to ignore the assessment of “relevant” endpoints in the compositional analysis. However, it should be highlighted that if there is no request for specific data, these will never be produced and available for building up databases. During the last years, a vast amount of data has been produced on several allergens but these data are not publicly available yet. This information can serve as the basis for further discussions in the direction to develop an appropriate database, as mentioned by the commenter. Therefore, the comments are very valid and additional discussion in this direction should be promoted. Finally, the relevance of natural variability of allergens is of
<table>
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<th>Importance not only in the risk assessment of GMOs but also in other areas such as allergen labelling and thresholds levels.</th>
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<td>6.6</td>
<td>What is the added value of an exposure assessment (to modified oil) for a stack when the previous assessment for the single event has already been conservative and not raised any red flags?</td>
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<td>Would you also consider asking for a probabilistic exposure estimation if the point estimates (deterministic &amp; conservative) still showed high values, similar to what is done for pesticide residues, for example?</td>
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<td>8</td>
<td>As regards the Conseil d'État ruling, this particularly also pertained to Clearfield canola obtained through anther/microspore culture, hence from the 80s/90s and considered &quot;unnatural&quot; by the applicants for the court case there given that whole plants are reproduced from aploid gametes. Will the Panel also consider these elements besides the molecular changes per se?</td>
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<td>Could the Commission/EFSA comment on the timeline set for the new mandate on random mutagenesis (in relation to the current procedure from France). Thank you</td>
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Could you pls. indicate which MS contributions on RA are analysed by EFSA in the framework of the mandate directed to support the KOM study

EFSA informed that there are 16 scientific opinions (SO) on the risk assessment of GM plant developed by new genomic techniques (NGTs) that have been provided by EC to EFSA from 8 MS. The size/content of these SOs varies. Some discuss only new SDN methods others discuss also older techniques like cis/intra-genesis. Based on the list of NGTs as devised in the JRC 2011 report that served as the baseline and also based on the NGT definition provided by EC in the mandate ToR, all NGTs are discussed by at least one MS opinion, except for synthetic genomics.

Annex IB of the GMO directive lists methods/techniques exempted and clearly states that they can be used in combination. The list includes mutagenesis and cell fusion/protoplast fusion. Since cell fusion and protoplast fusion cannot be separated from in vitro culture, does the GMO directive not already imply that the combination of mutagenesis and in vitro culture are exempted from its scope?

The ruling from the French Conseil d’Etat did not make the link as suggested by the observer. The interpretation of the legislative background is out of EFSA remit. EFSA will answer the EC request from a scientific perspective.

Out of agenda

Question as an EU citizen: EFSA stressed the need to perform RA within the legal framework and I would think that the risk assessment needs to take into account the general EU framework requiring proportionality, basing the precautionary principle on a credible hypothesis and taking into account animal welfare to conducting experiments but even to use public resources in efficient manner. How are these key principles taken into account by the Panel when an application comes in and how does a company receive feedback to a derogation request?

Sectoral legislations set the scene. Regarding animal health and welfare aspects, these were also discussed at EC level together with Member States. The concept of comparative analysis might need rethinking (selection of proper comparator: alternative practices, etc) in certain cases. Regarding the derogation request, these have to be justified by the applicant; if they concern risk assessment, those will be assessed by EFSA during the risk assessment.

I have a question regarding the minutes of the 137th plenary meeting of the GMO Panel – particularly for item #8, which included a summary of a presentation describing the outcome of the EFSA procurement on in silico protein toxicity prediction methods to support the food and feed risk assessment (NP/EFSA/GMO/2018/01).

- The outcome of the work will be published following EFSA’s standard practice for procurement work, i.e. in the form of an external scientific report.
- Additional-supplementary material such as information collections produced from
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<th>I don’t know if there will be a follow-up to that point in today’s meeting (maybe as part of agenda items # 7 or 8?), and/or if the following questions would fit within the scope of today’s meeting, but I would welcome feedback on these, either online or offline:</th>
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<td>• Would the results of the work performed be shared in more detailed in a scientific publication or other format?</td>
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<td>• Would the resources generated be made publicly available for use? (eg. Database(s) generated for use as “knowledgebase”; list of freely available in silico toxicity prediction tools)</td>
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<tr>
<td>• Can you clarify what are the next steps regarding this work on in silico protein toxicity prediction methods?</td>
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<td>scrutinised databases will also be publicly available. It is noted that no in silico prediction tool has actually been produced.</td>
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<tr>
<td>The data collected for this work can form the basis for further information gathering in order to identify those protein structural/functional elements relevant in the molecular initiating events leading to toxicity. These data may also contribute to the development of a comprehensive in silico risk assessment strategy in a broader aim of setting new risk assessment strategies for new proteins.</td>
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### 10. Adoption of the minutes and next meeting

The minutes of the current meeting were adopted by written procedure and will be published at: [http://www.efsa.europa.eu/en/events/event/138th-plenary-meeting-gmo-panel-open-observers](http://www.efsa.europa.eu/en/events/event/138th-plenary-meeting-gmo-panel-open-observers)

The 139th GMO Plenary meeting will be held by teleconference on 14-15 October 2020.