

Network on Pesticide Steering meeting Minutes of the 22th meeting

Held on 24-25 October 2017, Parma

(Agreed on 17 November 2017)¹

Participants

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

Country	Name²
Austria	Sonja ECKER
Belgium	Herman FONTIER
Czech Republic	Jana JEZKOVA
Denmark	Vibeke MØLLER
Finland	Kaija KALLIO-MANNILA
France	Léa RIFFAUT
Germany	Herbert KÖPP
Greece	Agathi CHARISTOU, Danae PITAROKILI
Hungary	Tamás GRIFF
Ireland	Tom MEDLYCOTT
Latvia	Līga BRENCE
Lithuania	Kristina VALIONIENE
Netherlands	Hanneke WESTLAND
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Portugal	Bento DE CARVALHO
Spain	José Luis ALONSO-PRADOS
Sweden	Katarina LUNDBERG
United Kingdom	Donal GRIFFIN
Turkey (Observer)	Tugba ADIGUZEL KARGIN Ahmet Uğur DURU

- European Commission DG SANTE (via tele-web conference):**

Wolfgang REINERT

Jérémie PINTE – participated in agenda point 8

¹ The publication of the minutes shall be made without delay in compliance with the Founding Regulation and no later than 15 working days following the day of their agreement.

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

- **EFSA:**

Pesticides Unit (José V. TARAZONA, Head of Unit, Chair)

Pesticides Unit (Bénédicte VAGENENDE, Coordination Team)

Pesticides Unit (Dimitra KARDASSI, Coordination Team)

Pesticides Unit (Tunde MOLNAR, Coordination Team)

Pesticides Unit (Alessia VERANI, Coordination Team)

Pesticides Unit (Angela SACCHI, Coordination Team)

Pesticides Unit (Luc MOHIMONT, Deputy Head of Unit) - participated in agenda point 17

Pesticides Unit (Rachel SHARP, Ecotoxicology Team) - participated in agenda point 19

Pesticides Unit (Alessio IPPOLITO, Ecotoxicology Team) - participated in agenda point 21

Pesticides Unit (Claudia Heppner, Residues Team) - participated in agenda point 9

Pesticides Unit (Jürgen STURMA, Coordination Team) - participated in agenda point 11

Legal & Assurance Services Unit (Dirk Detken, Head of Unit) - participated in agenda point 13

Legal & Assurance Services Unit (Simone Gabbi) - participated in agenda point 13

Scientific Committee & Emerging Risks Unit (Reinhilde Schoonjans) - participated in agenda point 4

Applications Desk Unit (Simona Radulescu) - participated in agenda point 3

1. Welcome and apologies for absence

The Chair welcomed the participants including the observers from Turkey who attended the PSN meeting for the first time.

2. Adoption of agenda

The agenda was adopted with the following modification: for the request of NL agenda point 12 has been postponed to a later meeting. The additional point raised by EL regarding genotoxicity of formulations will be covered by the Pesticides Peer Review Experts' meeting 170 on mammalian toxicology where a general agenda point has been added on this topic (11-14 December 2017).

3. GLP activities in EFSA (APDESK)

EFSA gave a presentation on GLP activities coordinated by EFSA, in particular on the implementation of EFSA's GLP Studies Audit Programme in support of the evaluation of regulated products. Around 500 applications are received across

EFSA every year, among which a significant number of GLP studies are submitted by applicants on a mandatory or voluntary basis. According to the SOP_022 "*Selection of studies performed in compliance with GLP requirements for audit purposes*" EFSA can request either *ad hoc* audits whenever it has a justifiable reason, or routine audits that are more general and are undertaken on a yearly basis. In both cases the audits are performed by the Monitoring Authorities from the Member States (MA-MS). It was clarified that audits can be requested in both EU and non-EU (OECD) countries. 2016 was the first year when EFSA implemented such an audit programme in line with the SOP_022. EFSA gave a brief overview on the outcome of this exercise, which covered 3 areas of regulated products: food ingredients and packaging, feed additives and pesticides. Altogether 13 studies were selected, including 7 studies for pesticides (covering residues and ecotox areas). As an outcome, it was highlighted that the majority of the studies audited were found to be in compliance with GLP while 2 cases of non-compliance in the feed additives area were for administrative reasons. The EFSA's Report on GLP Studies Audit Programme is currently not yet publicly available. EFSA appreciated the great collaboration achieved with MA-MS during this exercise which is also considered as a key element to increase the number of studies to be audited. In addition, good cooperation has been established with EC (DG GROWTH) who follows the EFSA activities on GLP and experience has been shared also with other decentralised agencies (EMA, ECHA) in this field. In 2017, a higher number of studies have been selected for audit, including 8 studies for pesticides, with higher number of MSs involved. New regulated areas have also been introduced into the programme. In general, the programme together with the network developed with EC and MSs were considered a great achievement to contribute to the quality of data submitted with the applications and on which the EFSA's risk assessment is based.

Action:

- MSs are invited to flag to EFSA any particular study where they identify a concern for potential inclusion into the yearly audit. As regards status of GLP studies, MSs are advised to liaise with their national monitoring authorities in the first instance.

4. Update of Scientific Committee Guidance Document on nanotechnology

EFSA gave a presentation on the draft EFSA guidance on the risk assessment of the application of nanotechnologies in the food and feed chain developed by the EFSA Scientific Committee. The guidance aims to cover various areas under the remit of EFSA that are confronted with nanotechnologies, such as novel foods, food contact materials, food and feed additives and nanopesticides. Nanomaterials are defined to be in the size range of 1-100 nm, however, from risk assessment point of view and for safety considerations, the guidance aims to cover also small particles above this defined size range. For the time being the guidance is focusing on human health aspects by considering oral, dermal and inhalation exposure, while environmental aspects such as non-target organisms, ecotoxicology, fate and behaviour are planned to be covered in a second phase starting end 2018. With regard to nanopesticides, currently there is no legal definition. The term "nanopesticide" used in the guidance covers nano plant protection product active substances, its co-formulants and the formulations (i.e. plant protection products). A possible definition based only on

the size in the nano-scale (i.e. 1-100nm) could however exclude many recent formulations that are larger (e.g. "nanoemulsions formulation"), while some formulations (e.g. "microemulsion formulation") may contain fractions in the 1-100 nm range that have been on the market for a long time without previously being classified as "nano". The guidance is aimed to be used by both EFSA and MSs in the context of the risk assessment of active substances, co-formulants and formulations, in particular when a nanomaterial is used in a PPP, e.g. as a co-formulant or synergist. It is recommended to follow this guidance for both food safety as well as application safety (operators, workers, bystanders and residents) assessments. With regard to the timelines, as the next step, a public consultation is envisaged to be launched in January 2018. The guidance is foreseen to be adopted by the Scientific Committee in July 2018.

Overall, the PSN members felt that the impact of this guidance on product authorisation at national level is at present unclear, and raised concerns as regards the lack of legal basis for asking nano-specific data in the absence of relevant data requirements. EC expressed concerns over the legal uncertainty on the use of the guidance potentially leading to data gaps or critical areas of concerns in the EFSA Conclusions. It was clarified that for the time being the guidance relating to pesticides will contain EFSA's recommendations only. The guidance aims to put forward a new approach for which the regulatory framework should be taken into account in the future by EC/MSs. Currently it is premature to start such discussions, once the guidance is finalized, risk managers should decide on the need for possible formal implementation and regulatory endorsement and on the necessary legal actions to take.

Action:

- MSs are invited to share their views and submit comments on the draft guidance during the public consultation. A notification will be sent to PSN members upon opening of the public consultation.

5. Presentation of the Technical Report on the Action Plan for improving the EU peer-review on pesticides active substances; incl. feedback on new excel commenting table (pilot pydiflumetofen)

As a follow up from previous meetings, a Technical Report has been drafted by EFSA on the action plan for improving the peer review process on pesticides active substances. The document serves as a brief summary of the main actions and outcome of the extensive discussions held over the previous meetings and will be published on EFSA's website for access by all stakeholders.

EFSA briefly presented the Technical Report that covers the various steps of the peer review process from preparation of the summary dossier by the applicant, preparation of the Draft/Renewal Assessment Report, as well as actions related to the EFSA peer review and the finalisation of the EFSA conclusion. In this context, a short update was also given on the developments of the Working Group on 'accordance check', which has been recently established with participants from several MSs, EFSA and ECHA. The primary focus of the group is in the first instance to agree on EU wide criteria for good quality summary dossier and DAR/RARs, while the implementation aspects with specific roles and timelines will be defined in a second phase. MSs who are interested to join the WG, can still do so.

To further streamline the peer review process, a new excel template has been developed by EFSA aiming to replace the previous commenting tables, reporting table, evaluation tables and report on written procedure on additional information. Having an excel based format, the new commenting tool has also the benefit to allow functionalities such as searching, sorting, filtering etc. It is a living document which will be updated continuously with the evolution of the peer review process. The new commenting tool was distributed to MSs on 25 September 2017 and a pilot is currently ongoing in the peer review of pydiflumetofen (RMS: FR).

PSN members shared their experience with the new approach EFSA is following in the recent pesticides peer review meetings, such as allocating substances to specific experts who are invited to submit written contributions in advance of the meeting. It was clarified that the main purpose is to facilitate the discussions and the submitted preliminary comments may not be the formal and final views of the experts. In view of transparency, these preliminary comments will be entered into the meeting report and will be published at the end of the process as part of the background documents to the conclusion. It is acknowledged that this process is also new for EFSA and some time may still be needed until it is fully implemented and run smoothly. Also, as an *ad hoc* approach, due to time constraints and/or additional evidence that may have arisen and could not be considered in the meeting, a post-meeting consultation via written procedure may take place. It was acknowledged that critical issues should ideally be agreed during the expert meeting, and in case no clear majority can be reached, a second consultation may be considered on a case-by-case basis. It was however agreed that such a second consultation should only be conducted in exceptional cases. EFSA will endeavour to transparently report the outcome of the expert meetings in the EFSA Conclusions, and, irrespective of the outcome, EFSA also seeks to reflect the EFSA view in the Conclusions.

As regards the next steps in the finalisation of the action plan, PSN members are invited to provide written comments on the draft Technical Report by 17 November 2017. The finalized Technical Report is envisaged to be published and presented to the PAFF Standing Committee in December 2017.

Action:

- MSs to provide written comments on the Technical Report by 17 November 2017.
- MSs are also invited to share their first experience with the new commenting tool.

6. Peer review work program, focussing on renewals

EFSA gave an update on the current practice of processing incoming assessment reports in the peer review. For the time being 4 new DARs/RARs per month are launched for commenting to ensure sufficient coverage by relevant experts, with priority given to DARs. It is acknowledged that the list of a.s. for which the DAR/RARs have been submitted and for which the peer review should still be initiated is becoming longer, in particular that a high number of DARs/RARs are still expected to be received by the end of the year. It was explained that in most cases these are complex substances with extensive reporting tables leading to significantly higher volumes of work in general, which regularly results in significant delays and the need for EFSA to request extension of the overall

timelines. The PSN members confirmed that with these complex substances they often face difficulties in respecting the standard timelines, also in view of the extent of data produced by the applicants during the stop clock. It was suggested that during the commenting focus should be put on the important elements while editorial comments often made by applicants should rather be avoided e.g. by earlier consultation with the applicant potentially during the finalisation of the DAR/RAR. MSs shared their experience (which included also difficulties and further delays caused by such consultation) and highlighted different practices currently in place.

A quick update was given on the status of the common AR/CLH report template and MSs shared their experiences on its use. The common template has been taken note at the PAFF Standing Committee meeting in October 2017 while the proposed amendment of Regulation 844/2012 (i.e. mandatory submission of CLH report for all renewal applications) is still under discussions.

For the time being MSs seem to follow different approach in applying the combined template. In particular MSs, with different agencies responsible for the PPP and CLH procedures, reiterated their difficulties with the preparation and harmonised submission of the report to both ECHA and EFSA in a timely manner. Overall, MSs felt that more time should be allocated for the preparation of the assessment reports and suggested that the timelines in the legislation should be reconsidered accordingly.

It was agreed that proper planning is essential for the alignment. As a possible way forward, EFSA is proposing that once the accordance check by ECHA has been completed, a common public consultation should be launched. Clarifications were requested by MSs considering the case in which additional information are required during the accordance check of ECHA, and/or when additional information is requested by EFSA during the peer review. EFSA will further consider the option of submitting comments to the RMS for general improvement of the assessment, as currently under discussion in the WG on Accordance check. All comments relating to classification and labelling are proposed to be forwarded to ECHA for further consideration by the RAC Committee while EFSA would simply refer to the RAC decision in its Conclusions. Further discussions on the alignment of the EFSA and ECHA CLH procedure will soon re-commence. In the meantime, the RMSs will be asked by EFSA for an update on the CLH report status whenever a new DAR/RAR is received. EFSA will take this information into account when planning the peer review initiation dates and will endeavour to align both processes as far as possible.

MSs expressed concerns on the possible impact of this alignment on timelines (currently ECHA accordance check is unpredictable and takes 2 to 6 months) and related to a.s. expiration deadlines EC clarified that, in view of efficiency gain, it is preferable to align the processes at the earliest stage as possible in order to avoid further delays at risk management phase. In general, MSs flagged the need of further written instructions/guidance on the transitional measures once the discussions between EFSA and ECHA will be finalised.

7. Human biomonitoring project: prioritisation for some a.s (proposed by EC)

EC informed PSN on the human biomonitoring project. The European Human Biomonitoring Initiative launched in 2016 by European Commission DG Research

is a joint effort of MS countries and the European Commission led by a project consortium. The main aim of the initiative is to coordinate and advance human biomonitoring in Europe and thereby provide better evidence of the actual exposure of citizens to chemicals and the possible health effects to support policy making. Substance groups nominated to be the subject of the project for 2017 includes bisphenols, per-/polyfluorinated compounds, flame retardants, cadmium and chromium VI.

Next round of prioritisation exercise will be conducted in 2018. Commission will generate a short list of 30 substance groups, out of which 10 will be selected for the human biomonitoring project. Inputs will be gathered by General Directives within Commission, MS Agencies, EFSA and other stakeholders. DG SANTE has identified possible substances in the list, 3 active substances: glyphosate, fipronil, dimethoate/omethoate, 3 metabolites: triazole derivative metabolites, triazine amine, aniline and 1 co-formulant: tallowamines ethoxylated/propoxylated.

Human biomonitoring data are of particular importance in exposure assessment. Further development of biomonitoring of exposure is needed to monitor substances of interest for EFSA. EFSA had proposed the creation of a small WG focusing on pesticides aiming to identify active substances for human biomonitoring analysis based on their toxicokinetics. A multiple screening system could promote simultaneous checking of active substances and metabolites. Internal exposure from human biomonitoring data could be combined with the external exposure data from the pesticides monitoring program (pesticides residues levels in or on food and feed) conducted by MS at yearly basis. EFSA proposed to prioritise substances in the biomonitoring program that are already included in the pesticides monitoring program in order to conduct realistic exposure and thus help to "validate" dietary exposure estimates and also detect health effects.

MS were asked to share the information as appropriate. EC will inform MSs on the substances selected for the next round of prioritisation exercise, when available.

8. Update on unacceptable co-formulants (proposed by EC, via TC)

EC provided an overview of the current situation and background for co-formulants at EU level. A feedback from the on-going EU working group (WG) on unacceptable co-formulants (last meeting 24-25 October 2017) was also reported. The main aim of the WG is to establish a procedure for the inclusion of unacceptable co-formulants in Annex III of Regulation (EC) No 1107/2009 according to the provisions stipulated in Article 27 of the Regulation. The purpose is to achieve a harmonised approach at EU level on the identification of unacceptable co-formulants in plant protection products (PPPs), in synergism with other Regulations as REACH/Biocides. The WG is currently working on two draft acts: the first to establish the criteria and procedure for evaluation of candidates for inclusion to Annex III; the second to identify the first batch of unacceptable candidates (approximately 90 candidates). The data and hazard identification would be performed based on REACH/CLP provisions while the evaluation could be a mixed approach. The decision could be undertaken under PPR or REACH regulation, based on the specific cases. Under this point MSs

flagged the need of full access to the REACH dossiers and related data, since information as regards co-formulants is currently just partially covered under PPP.

A first outline of the procedure was also proposed, referring to confirmatory data procedure under Pesticides Peer Review as an example, however after last WG meeting discussion, this point has to be totally reconsidered. Finalisation of the draft regulations is envisaged for the 1st half of 2018.

9. Update on:

Art. 4.7 procedure and protocol

Art. 53 mandate emergency authorisations neonicotinoids

EFSA gave an update on the activities currently undertaken under Article 4(7) as well as on the new mandate received under Article 53 of Regulation (EC) No 1107/2009. Article 4(7) of Regulation (EC) No 1107/2009 provides a derogation from the standard approval criteria to allow for consideration of the approval of active substances which are necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, but may be non-approved based on the hazard based 'cut-off' criteria, even if there is an acceptable risk assessment. It was highlighted that this procedure is restricted solely for cases when the Annex II points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 are not satisfied based on harmonised or proposed classifications during peer review and when an acceptable risk assessment is demonstrated. It was clearly highlighted that it is not intended to override deficient data packages or failing risk assessments. This derogation does not apply to substances that are classified as Carc Cat 1A, 1B without a threshold, or Repro Cat 1A. A brief overview was given on the different steps and actors involved in the procedure. There are two situations in which applicants may submit information to demonstrate that Article 4(7) can be applied i) when an active substance already has harmonised classification in accordance with Regulation (EC) No 1272/2008 or ii) when the peer review of the active substance propose a classification in accordance with the provisions of Regulation (EC) No 1272/2008. The RMS and MSs play an important role in the evaluation of the applicant's submission as well as in the validation of the data including confirmation that the uses requested by the applicant are authorised and considered essential to control a serious danger to plant health. For the applications received so far EFSA rather than the RMS requested all the MSs to verify the information. It was stressed that MSs have the full responsibility for the accuracy and correctness of the data provided to EFSA during the procedure.

The first substance considered within the context of the Art 4(7) procedure was flumioxazin, a herbicide active substance. EFSA allocated the mandate to its Animal and Plant Health (ALPHA) Unit and a dedicated working group has been established to develop a common methodology for the evaluation of herbicides. Upon completion of the work, the herbicide protocol was published on 2/08/2016, and following the same exercise lead by the ALPHA Unit, the insecticide protocol was also completed and published on 5/04/2017. Currently, the fungicide protocol is under finalization with expected publication in November 2017. To date, 3 scientific reports have been produced by EFSA under the Art 4(7) procedure (flumioxazin, flupyrifluron-methyl, isoxaflutole). An application has already been received for pymetrozine (insecticide) and the

scientific report is currently under finalisation (deadline December 2017), and further fungicide applications (e.g. epoxiconazole) may also be expected.

EFSA briefly outlined the principles of methodology as described in the protocols, in particular for the evaluation of chemical and non-chemical alternatives, including considerations of mode of action and analysis of resistance. It was clarified that efficacy should also be taken into account, however it is not intended to undertake an in-depth efficacy assessment during this exercise. Following the first experiences, further considerations and improvements to the process may be made in the future with special regard to the assessment of mixtures, the extent of flexibility needed when applying the methodology, the amount of a.s. data to be listed, or practical improvements in the data collection sheet.

As regards future improvements and development of these processes, the PSN members welcomed the idea of potentially producing a consolidated methodology covering the various types of pesticide active substances when further experience is gained over time. It was agreed that for the time being this is still premature and further experience is needed on the application of all three groups of protocols prior to the establishment of a consolidated guidance.

MSs raised questions as regards the content of the assessment reports when the 'cut-off' criteria are met. It was acknowledged that for the time being there is no clear guidance on the approach to be applied and different level of information may be available in the dossier depending on whether harmonized classification is already available or in case the classification leading to the 'cut-off' criteria being met is only proposed during the peer review. It was agreed that in case harmonized classification under Regulation 1272/2008 is already available showing the 'cut-off' criteria fulfilled, a case-by-case consideration is needed for the preparation of the RAR and it is recommended to contact EC and EFSA to discuss the specific case. So far EFSA received only one RAR with targeted assessment (quinoxyfen) where the assessment report was limited to PBT assessment only. For the time being no approval has been granted under the provisions of Article 4(7). Risk managers will need to consider the approval conditions following an Art 4(7) assessment case-by-case and it is expected that any approval may be restricted to specific crops/pest combinations and/or to limited areas and MSs.

Finally, an update was given on the new mandate received on 15/9/2017 under Art 53 of Reg 1107/2009 to assess the emergency authorisations for the use of 3 neonicotinoid a.s. (clothianidin, imidacloprid, thiamethoxam) granted by 7 MSs (Romania, Bulgaria, Estonia, Finland, Latvia, Lithuania and Hungary). EFSA will issue seven technical reports concluding whether these authorisations were necessary due to danger which could not be contained by other reasonable means. On 23/10/2017 a conference call was held with interested MSs providing a short overview of the methodology and practical assistance with the data collection forms. The deadline for the delivery of the technical reports is 15/05/2018.

Action:

- In the context of the mandate under Art 53, concerned MSs are requested to provide to EFSA the reporting tables and data collection forms by 15/01/2018.

10. Micro-organisms: piloting parallel assessment a.s. and PPP

MSs were informed of a proposal made by the association of manufacturers producing microorganisms as plant protection products (IBMA). Industry would be interested in piloting an application to include both a potentially low-risk active substance and product. A complete assessment of a low-risk active substance and products should be included in the RMS assessment and the subsequent peer review. The proposal for a complete assessment of low-risk active substances and plant protection products was presented in the workshop of the Commission WG on Sustainable Plant Protection. With the above proposal the DAR and the EFSA peer review will also assess the product for the authorisation at the same time as the substance. The applicant should propose the relevant uses and the representative formulations, however more uses and products in the substance dossier should be encouraged in such case.

PSN members did not confirm that they were approached by applicant(s) on such proposal, however the feasibility of a possible pilot was discussed. The advantage of such procedure is that the information on one or more products is readily available during the active substance assessment, and thus will facilitate the subsequent decision making at MS and zonal level. It was clarified that a possible pilot would be applied for a new active substance and not for microorganism falling under the AIR IV program, and that the regulatory framework for the approval decision would not change. The proposal to include the complete assessment of the product in the RMS assessment and the peer review is aiming to facilitate the process and it will be more efficient if several representative formulations, efficacy assessments and mitigations measures would be presented in the assessment. EFSA noted that as already agreed all the studies presented in the assessment report will be peer reviewed.

Some MSs asked to reflect on the proposal while other acknowledged that this procedure would facilitate the decision making at MS and zonal level. A possible pilot may be conducted by the RMS after being requested by applicant(s).

11. MATRIX:

- update on progress**
- feedback pilot with external stakeholders**
- hosting of PPP dossiers**

EFSA gave an update on the progress of the MATRIX (e-submission and electronic workflows) project. The state of play and next steps were presented and discussed.

The implementation phase of MATRIX started in August 2016, first phase of the project "MATRIX Phase 1 - Stage 1" focuses only on for the food sector areas PRAS, GMO and FEED. The emphasis during this phase was on the structure of the dossiers, a file transfer system and the development of administrative workflows. The development of the test environment is also finalised for the integration test and the pilot phase.

A rough overview of the next steps was presented. "Stage 2" of the project should start in January 2018, "go in production" for the 3 EFSA piloting units (PRAS, GMO and FEED) will be launched in July 2018. In parallel, build and test

the remaining food sector areas (NUTRI, FIP, and Biocontam) and a pilot for the remaining sectors is planned for December 2018. The remaining sectors will "go in production" by July 2019, however this is still a rough estimation.

The project will implement a full electronic submission of dossiers, automated administrative workflows and improved communication. The project will also analyse and prepare for possible automation of publication of non-confidential parts of the dossier for applicable sector areas. The new dossier structure has a XML backbone based on a modified GHSTS standard (OECD Globally Harmonised Submission and Transport Standard). EFSA's change requests to adjust the GHSTS standard were negotiated with OECD and those changes accepted have already been implemented into the modified GHSTS.

The system will also make use of additional files and metadata, namely SSD2 (EFSA Standard Sample Description) for the reporting of raw data and OHTs (OECD Harmonised Templates) for Reporting Chemical Test Summaries. Applicants will benefit from the delivery of structured data in the form of OECD Harmonised Templates and the transport of "raw data" and other file types that may be required in the evaluation of submissions. Small and medium companies may benefit from the free dossier Builder tool which will be available towards the end of the project, to facilitate the dossier submission.

Automated dossiers transfer protocols and workflows piloted for GMO, PRAS and FEED food sector areas have been finalised. File transfer for the dossiers that will be submitted to EFSA is implemented by configuring Axway. An automated technical validation step will follow to check whether the dossier format is compliant with the XML structure. In case of successful validation, the dossier will be automatically stored into EFSA's DMS (Document Management System)

Next step: Workflows and communication. Administrative workflows have been designed for all core business and food areas involving external stakeholders. Notifications to the end users would be automatically created including flagging of deadlines. Communication is re-designed to be automated as far as possible. EFSA has established the Discussion Group 1 to discuss and consult external stakeholders, including some MS, on the technical aspects of the MATRIX Project. Different IT-tools are used for internal and external communication (Appian and Salesforce respectively). Tasks will be communicated through the Salesforce interface to MS/RMS/Applicants. The MATRIX tools have to be integrated into EFSA's IT tools, need for communication of Salesforce and Appian through the EFSA's centralised Oracle service bus has created severe problems and delays. Due to the technical issues, the pilot with external stakeholders has been postponed, next pilot with EFSA staff for dossier submission and workflows will run end of October.

PSN members were informed that Commission has started the development of a similar project for PPP dossiers submission. EFSA noted that these 2 systems should communicate with each other or ideally be integrated. It is not yet clear if EFSA or EC will host the dossier submission for PPP. Further discussion with EC is needed. A single central repository and integrated workflows for both systems would be preferred.

EFSA clarified that the first dossier submissions through MATRIX for pesticides active substances would not be expected before mid-2019 provided that Viewer and Builder should also be available. Applicants will be given adequate time to

adjust to the new dossier format. The system will be released at first place for NAS only.

Further discussion took place. ECHA uses similar system for electronic dossier submission (IUCLID), however this system was build up to carry on xml data and has now been extended to also receive attachments. Pesticides dossier are based on different requirements, mainly containing pdf formats, MATRIX is designed to transfer both xml data and pdf formats. The project will make benefit of IUCLID functionalities in the next steps, nonetheless the system will be compatible with IUCLID. EFSA clarified that the system is cloud-based and there will be not need installation of specific software for the users.

Clarifications were sought regarding the ongoing work on the accordance check which has been recently established with participants from several MSs, EFSA and ECHA. EFSA confirmed that the outcome of the Working Group on 'accordance check' criteria for good quality summary dossier and DAR/RARs will be also taken on board in the project. EFSA reiterated the advantage of having xml data and SSD2 raw data, easier access to data and automatic checking can be readily implemented. The system should be flexible. Based on the outcome of the 'accordance check' WG, further discussion on which parts could be checked automatically, may be needed. Further consideration merits also the confidentiality claims and which parts could be filtered automatically through the system. The Discussion Group 2 is focused on the confidential information.

EFSA invited MS to reflect on the proposal for a single central repository hosting a.s. and PPP dossiers.

Action points:

- MS to provide comments/feedback to EFSA on the proposal of hosting all a.s. and PPP dossiers on one central repository.

12. How to assess in situ generated active substances (proposed by NL)

Postponed.

13. EFSA Policy on Independence

EFSA (Legal and Assurance Service Unit) gave an update on the new EFSA policy on independence. In June 2017, EFSA's Management Board (MB) adopted a new [Independence Policy](#), providing a clear framework for the way in which EFSA manages the interests of its scientific experts and others with whom it works. Underpinning the Independence Policy is a set of rules that detail how EFSA will implement the Policy in practice and that provides guidance to scientific experts and others on how to declare relevant interests and how they will be assessed by EFSA to prevent conflicts. The new Policy builds on EFSA's experience of managing interests over the last 15 years as well as on input received from stakeholders, the European Parliament and the general public. The rules also outline the enforcement measures EFSA will take in case the rules are breached and how transparency will be ensured throughout the process.

The policy requirements of EFSA originate from the Article 298 Treaty on the Functioning of the EU and the Article 41 of Charter on Fundamental Rights of EU Regulation (EC) No 178/2002 and are common to all EU administration.

A risk-based approach to prevent the occurrence of conflicts of interest is presented in the MB decision. By this approach EFSA identifies qualified and unconditional restrictions that are applicable to professionals involved in its scientific activities. In this way, the Authority ensures that this policy does not hinder the availability of expertise needed to accomplish EFSA's duties in line with the principle of scientific excellence. EFSA enforces a two years cooling off period on pursuing private or commercial interests including managerial, employment, scientific advisory and consultancy activities. EFSA will systematically create engagement opportunities for interested parties to explain how it manages experts' interests and to address specific concerns.

A [Decision of the Executive Director](#) implementing the Policy was published recently and lays down the rules on the establishment and the implementation of a system for managing competing interests and ensuring the prevention of conflicts of interests within EFSA. This Decision is applicable to all professionals involved in EFSA's scientific operations, including external experts, members of the peer review meetings, network members, hearing experts, observers etc. As per the rules already in place, ADoIs for the members of Advisory Forum and members of Networks, are published; no screening, assessment or validation is performed by EFSA. For the members of Scientific Committee, Scientific Panels, Working Groups, the ADoIs are screened and evaluated by EFSA for identification and prevention of CoI. ADoIs are published and where needed, Oral Declaration of Interest (ODoI) is given by the Experts. A new feature involves the Participants to peer review meetings, including MS representatives, where the same approach for the ADoI screening and evaluation is applied. The rules outline that the pesticide experts from national authorities are subject to the same transparency and DoI screening rules as experts on EFSA's Scientific Committee, Scientific Panels and Working Groups. The decision acknowledges that activities carried out by experts as part of their public interest engagement with their respective public institution(s) in the Member States' or in other international public organisations do not constitute a source of CoI with EFSA's activities under this decision. An exception concerns the risk management functions that are performed by the experts with public institutes on the same subject discussed in the EFSA scientific groups and are ongoing, or terminated in the two year prior to DoI submission. For members of networks and of the Advisory Forum, a trust-based approach is applied to experts working for public institutions resulting in no screening and ex ante clearance for all interests for representatives of MS and international public organisations, unless EFSA is made aware of a CoI. MS noted that the process should not create delays or additional administrative burden on the organisation of the meetings acknowledging the unpredictability of the work plan in the pesticides area and eventually of the a.s. to be discussed in each meeting.

MS raised concerns with regard to the performance of risk management functions. This is mainly the case for MSs with less resources deployed in the relevant sectors, when both activities are often conducted by the same entity or where there is no clear separation between risk assessment/risk management and as a consequence the same expert(s) may be involved in the assessment of the a.s. and the authorisation of the PPP. Legal and Assurance Unit of EFSA presented an example of possible exclusion. An expert within Public Institution might be considered not eligible to participate in peer review meetings when having risk management responsibilities coinciding with the subject matter of

the relevant EFSA group (i.e. discussion on renewal of an a.s. and /approval of a PPP having the same a.s. at national level). This decision would not exclude the expert from discussions on other topics or substances for which he/she is not responsible. It was clarified that in the ADoI the possible risk management engagement should be declared and preferable on specific dossiers in order to establish whether a CoI is identified in the peer review discussions. The rules will apply to all MS including RMS.

It was reassured that the aim of the exercise is to restrict the exclusion to cases where concrete overlap is identified. MS also raised the potential impact in a decrease in terms of efficiency. It would be more effective and time/resource saving if MS experts with experience in assessing the substance would be also involved in the evaluation of the PPP.

Next step: The Advisory Forum (AF) WG on Independence and DoIs will conduct a mapping exercise to improve reciprocal understanding and to the extent possible identify common grounds. Next steps involve training for assessors, and update of internal standards. The new decision concerning the pesticides peer review assessment will enter into force as of 1 July 2018. It was commented that the new Policy may need additional discussion between the competent authorities for pesticides assessment.

Action:

- PSN members to express their interest to participate in a WG on the implementation of the rules relevant for the peer review meetings.

Access to 'pesticides studies'

EFSA's Legal and Assurance Unit gave a short presentation on the access to 'pesticides studies': best practices to improve the assessment. It was explained that the driver on this access request is the PAD Regulation³ & Aarhus Regulation⁴ and recent case-law development on the concept of 'information on emissions into the environment'. EFSA stressed that there is an increase in the number of access requests asking for 'pesticides' studies. A concrete case was referred: Access to documents request from a NGO on the ecotoxicological studies on two substances, prior national authorisation in the Member States. One of the substances was authorised in one Member State, however, the information on authorisation was not in EFSA's possession. To get all relevant information to perform the assessment on the accessibility of the studies both in compliance with the PAD Regulation and the Aarhus Regulation there is need for an 'alert' on national authorisation upon EFSA's request, best practice should be agreed.

EFSA Legal and Assurance Unit will set up a mechanism to engage and get the information from MS when there are product authorisations in the pipeline. Also EFSA examines whether the studies on request are related to the uses where the 'information on emissions into the environment' is relevant. It was noted that overlapping requests are also sent to MS and EC, however, this does not deprive

³ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents. OJ L 145, 31.5.2001, p. 43–48.

⁴ Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies. OJ L 264, 25.9.2006, p. 13–19

EFSA of the legal obligation to respond to the PAD request. It was clarified that the access requests asking for 'pesticides' studies does not mean the studies can be used by the requestor since the data protection should be respected.

Action point:

- EFSA Legal and Assurance Unit to collect information on relevant contact points dealing with PAD requests in MSs and create a network for quick exchange of information on overlapping PAD requests.

14. Feedback from Pesticides Peer Review 158 special meeting on residues and MRLs

EFSA gave a presentation on the feedback from the Pesticides Peer Review 158 special meeting on residues and MRLs. As already anticipated from the action plan, general and recurring issues are discussed in general experts meetings. EFSA identified several general issues in the area of residues which deserved experts' consultation and agreement in order to enhance the harmonisation of the risk assessment of active substances. The general PPR meeting 158 on residues and maximum residue levels was held in Parma from 3 to 5 May 2017. The following items were presented and discussed.

1. Guidance of the PPR Panel on the establishment of the residue definition to be used for dietary risk assessment (EFSA Journal 2016;14(12):4549). A training as combination of lectures and case studies took place. The principles of how to assess exposure in case the TTC approach would be applied and how to calculate the toxicological burden and select the representatives for the RD were explained on the basis of case studies (isoproturon and spiroxamine included in the guidance document plus a couple of additional examples). EFSA underlined that the guidance should be used as an entity and individual elements should not be picked out from the guidance.
2. The proportionality concept. The proportionality concept developed by JMPR was one of the topics identified where further discussions with MS are needed to ensure that MS and EFSA have a common approach to apply the provisions for scaling of residue trials in a consistent manner. A Draft Technical Report for application of the proportionality concept was produced by EFSA as a result of the discussion. MS were invited to provide comments on the draft Technical Report (TR). The TR reflects the outcome of the discussions and agreements regarding the principles and guidance for application of the proportionality concept in the risk assessment methodologies used at EU level for the estimation of the MRLs for pesticides. Different case studies are presented in the Appendix A of the TR. Recommendations on the proportionality concept as defined at Codex level are adopted at EU level (PAFF 09/2015). Experts discussed specific cases not fully covered by the general principles of the proportionality concept described in the OECD GD on crop field trials (2016) or that lead to different interpretation among experts. Different cases are illustrated in the document where the scaling is appropriate/not appropriate facilitating the interpretation on ambiguous cases. Following the MS comments, the TR will be published on the EFSA website.
3. Structure and quality of residue section of DAR/RAR. A complete new assessment report should be prepared instead of an addendum to the original

DAR, meaning one single document including the assessment of old data according to the template to be used for assessment reports (SANCO/12592/2012-rev.1). MS complained during the experts' meeting that the RMS does not have access to the old studies and the AIR III Guidance (SANCO/2012/11251 rev. 4) is unclear about the handling of old data in the context of the renewal procedure. It was agreed that the re-evaluation of the previously submitted and accepted old studies is needed on a case-by-case basis when end-points critical for the assessment are identified. MS agreed that in any case applicants should clearly demonstrate the reliability of the studies under the current scientific state of art, and present appropriate summary tables and results.

4. Animal dietary burden calculator. Presentation of the last updated version of the calculator (2017) – practical examples. The updated version of the animal dietary burden calculator is available on the COM website https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en. OECD consumption data should be used irrespective on the date of submission (i.e. also before 2014) (SCPAFF, June 2015).

5. Review of existing MRLs (Art.12) – new process. A training on the new process was recorded and it is available on the DMS for MS experts. According to the new process MS should initially notify GAPs without pre-screening, however, MS are requested to limit the number of GAPs per commodity and per MS (i.e. submit only 2-3 GAPs per crop to RMS). This would simplify the work of the RMS who has to identify the critical GAPs for each crop/for each geographical zone. Collection of data should be restricted to the most critical GAPs. MSs are invited to identify the critical GAPs among the authorised national GAPs (pre-screening of the authorised uses). In the experts' meeting it was discussed how to avoid duplication of work and take advantage of the zonal evaluation. At the time of the GAPs collection, MS can indicate in the GAP form that data are available in the zonal assessment uploaded on CIRCABC. When preparing the GAP overview file, the RMS can verify the data available in the zonal assessment mentioned in the GAP form and, in case data support the most critical GAP, report them in the Evaluation report submitted with the PROFile. In this way the data will be publically available and referenceable.

- Consolidated List of endpoints (LoEP) on residues.

EFSA informed the PSN members that a harmonised version of the LoEP residues (for peer review and MRL assessments) has been developed by the Residues Team of EFSA. This LoEP covers all EFSA outputs, regardless of the process (e.g. peer review or MRL assessments). It was stressed that the changes in the residues section are of editorial nature, including tables formatting and alignment between processes. The changes do not impact the assessment. EFSA proposed to implement the new streamlined LoEP in the template of the DAR/RAR in order that RMS/APPL could directly use it in their initial assessment. The new LoEP is also in alignment with the LOEP database under preparation in EFSA. MS were invited to provide comments (3 weeks commenting period), focus should be given on major issues that might have an impact on assessment. The MS commenting on the LoEP should facilitate the PAFF note taking in a forthcoming PAFF meeting.

Action points:

- MS to comment on the draft Technical Report on the proportionality concept by 3 November 2017.
- MS to comment on the harmonised LoEP on residues by 15 November 2017.

15. Literature search: discussion on comments provided by T. Tweedale for 4 AIR II RARs

EFSA informed on comments provided by T. Tweedale for 4 AIR II RARs and the allegations of missing information on the search of the scientific peer-reviewed open literature performed by the RMS and subsequently peer reviewed by EFSA. The comments by T. Tweedale have been communicated to the relevant RMSs for information.

EFSA underlined that the public consultation of the assessment report is the most appropriate time for interested parties to submit comments and reiterated that the literature search should be assessed in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature.

DE informed that BfR is preparing a publication describing the step-wise systematic approach to assess the relevance and reliability including the contribution of particular publications in the risk assessment.

EFSA and MSs accepted the proposal of PAN Europe for hearing in the next PSN meeting.

16. Discussion on requests for hearings with PSN (ECPA, T. Tweedale)

EFSA informed PSN members on the request from ECPA for a hearing with PSN. The request is related to the peer review improvement action plan.

EFSA and MSs accepted the request for hearing of ECPA on the next PSN meeting. The presentation of the specific items/questions to be discussed need to be prepared by the entities requesting the hearing and will be distributed well in advance of the meeting. In case EFSA receives additional requests from the other industry associations registered as EFSA stakeholders in the area of pesticides, the hearing can be extended to the other associations.

17. Status of development activities

EFSA presented an overview of the developmental activities currently on going and planned for 2018. A Scientific Opinion of the PPR Panel on the follow-up of the findings of the External Scientific report 'Literature review on epidemiological studies linking exposure to pesticides and health effects' has been recently adopted (September 2017). Three more scientific opinions are expected to be finalised in 2018 (i.e. Pesticides in food for infants and young children; State of toxicokinetic/toxicodynamic (TK/TD) modelling for regulatory risk assessment of pesticides for aquatic organisms; CRD guidance on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessments). In 2018, also the drafting of the scientific opinion on the State of the science of pesticide risk assessment for bats should start. As regards the Guidance documents: the Guidance on PECsoil was updated in October 2017 and three

other guidances are currently under drafting (Update of GD Risk assessment for birds and mammals from plant protection products; Risk assessments for active substances of plant protection products that have isomers; Endocrine Disruptors criteria). Two scientific reports are supposed to be finalised in between 2018/2019 (Cumulative Assessment Groups and Cumulative Risk Assessments for the effects of pesticides on the thyroid and the nervous system; FOCUS surface water repair action). EFSA also presented the different grants and procurements currently ongoing with closure in 2018 (e.g. software tool calculating PECs soils for permanent crops and crops grown in ridges; database of processing techniques and processing factors compatible with FoodEx2), alongside the call for proposals and tenders envisaged. Finally, an EFSA workshop on comparative inter-species in-vitro metabolism is foreseen in 2018 and an Open Call for data on the refinement of the exposure scenarios of the OPEX guidance of EFSA should be launched. It was acknowledged that some projects were moved to 2019 due to budget limitations.

18. Protection goals: way forward (proposed by EC)

EC outlined how in the pesticide area the specific protection goals (SPG) based on ecosystem services were suggested according to the methodology outlined in the [Scientific Opinion of EFSA⁵](#) (EFSA, 2010). In 2016 the [Scientific Committee present a Guidance⁶](#) to develop SPGs for environmental risk assessment in the area of EFSA remit (EFSA, 2016). Since 2010 Scientific Opinions of the EFSA PPR Panel take into consideration SPG definition, suggesting which SPGs are acceptable for the risk mangers decisions. EC acknowledged the benefits of applying this approach, even if some discrepancies are highlighted between the methods applied in the GD vs scientific opinions in the pesticide area. Currently the topic is on hold at EC, last PAFF meeting included the SPGs as clarification point of discussion in the agenda.

This agenda point will be included in the next PAFF Committee discussion foreseen in December 2017 or January 2018.

19. Risk assessment of formulation and second a.s. under peer review

EFSA reported that an inconsistent approach is applied by both Applicant and RMSs in the risk assessment of formulated products containing a second a.s. Moreover the RA of repress formulation in general was discussed. EFSA pointed out that in some cases the assessment cannot be completed also in reference to data gap definitions. This is relevant in particular in reference to the failure of one of the 2nd a.s. assessment and to chronic risk assessment. However an exception is applied for the studies on NTA and NTP were risk assessment is currently performed with formulated product. EFSA has asked MSs to provide their view on how they would like to proceed with formulations containing more

⁵ EFSA PPR Panel (Panel on Plant Protection Products and their Residues), 2010. Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002). EFSA Journal 2010;8(10):1821. [55 pp.] doi:10.2903/j.efsa.2010.1821

⁶ EFSA Scientific Committee, 2016. Guidance to develop specific protection goals options for environmental risk assessment at EFSA, in relation to biodiversity and ecosystem services. EFSA Journal 2016;14(6):4499, 50 pp. doi:10.2903/j.efsa.2016.4499

than one a.s. MS have expressed some concerns if the assessment would not be able to define data gaps, this may have implications on the safe use of the products. EC and EFSA agreed that the peer-review will focus on the risk assessment for the a.s. under consideration.

Action point:

- RMSs are invited to encourage APPL to choose a representative formulation containing only 1 a.s. If this is really not possible, RMS should flag that the representative formulation contains a 2nd a.s. at an early stage in the peer review process to EFSA and EC.

20. Neonicotinoids Art.21 reviews: short update

A summary of the entire process was provided. EFSA clarified the expected final steps and related timelines till finalisation and publication of the outputs. The final deadline for providing the EFSA conclusions is on 30/11/2017. After the standard procedure for removal of confidential information in accordance with Art. 63 of Regulation 1107/2009, three conclusions will be published alongside a technical report on the ad hoc methodology developed for the evaluation of the data. It was acknowledged that during the expert meeting of October 2017 several MSs flagged the need of a second round of commenting on the draft conclusions before finalisation. The option of extending the deadline for the period of time needed in order to run an additional commenting round with MSs, is currently under consideration by EC.

21. Ecological population modelling for refined aquatic risk assessment: need for dedicated experts

EFSA shared its view on the current evaluation of ecological population models used in environmental risk assessment. Models are often presented in the frame of the refinements of the environmental risk assessment (e.g. particularly relevant for the aquatic compartment) by the Applicant in the Dossiers. Assessment of such models require a tailored/specific expertise, therefore often the peer-review is not able to properly assess them. EFSA proposed to establish a Working Group (WG) of experts with the objective of evaluate the submitted models. WG expertise could be requested at different stage in the peer-review process, early-stage (during the preparation of the DAR/RAR, asking for a complete study assessment) or during the peer-review. This will allow increasing the expertise and harmonisation on models evaluation within MSs and EFSA, models that will increase in relevance in the near future (e.g. reduction of animal testing). For the time being even if some MSs highlight the fact that is preferable to have a GD first, this seems the most straightforward approach. RMS experts' participation is encouraged and tailored WG based on type of model is suggested. EFSA will give priority to the TD/TK models for the aquatic risk assessment. EFSA clarified the procedure for the nomination of the experts, while applicant involvement in the WG will be evaluated on a case-by-case upon RMS request, in line with the peer-review procedure. The procedure will be discussed internally and MSs will be informed accordingly.

22. Presentation and discussion of comments on the "EFSA proposal on the future of pesticide risk assessments, as contribution to REFIT exercise"

EFSA presented its proposal for improving the scientific assessment of pesticides as contribution to the REFIT exercise, covering Regulation 1107/2009 and Regulation 396/2005. First of all EFSA compared the two current Pesticides regulations and related advantages and general faced issues. Under Reg. 1107/2009 it seemed that most of the issues are linked to the dual system:

- active substance (a.s.) with an EU assessment and approval decision of the pesticide active substance;
- Plant Protection Product (PPP) with a MS/zonal assessment and pre-marketing authorisation of each formulation.

The benefits from a more centralised approach under Reg. 396/2005 (with reference to e.g. MSs authorised uses for products reported under Article 12 MRL review and post-authorisation monitoring) were acknowledged. EFSA has therefore considered how this approach could be extended to Reg. 1107/2009.

EFSA would propose that all a.s., PPPs and relevant co-formulants are assessed in one process coordinated at EU level, involving all MSs in order to have a centralised integrated collaborative EU risk assessment process. The scientific efforts should be focused on: harmonising the risk assessment process, including justified MS requirements, evaluating the scientific evidence (all studies evaluated at EU level), setting the "input values for risk assessment" and finally assessing and implementing the new scientific methodologies. The implementation of such changes would be ensured through a single IT frame, integrating all current calculators and future updates with the database of validated input values, including also agreed methods and models. It was clarified that the principle of the proposals would be to have first a pre-marketing assessment of pesticides (products, active substances and other ingredients) at EU level, then the risk assessment would be updated for any new authorisation requested and finally risks could be refined based on actual use and monitoring data.

A draft document on this proposal for REFIT has been prepared and distributed to the Panel and to the Pesticides Steering Network for commenting. Finalisation of the related Technical Report is foreseen for November 2017.

MSs welcomed the proposal, considering it very interesting as much as very challenging. EC reiterated that the general scope of the REFIT process is to check the fitness of EU legislations, in order to ensure that specific regulations still 'fit for purpose' and that the regulatory burdens are minimised, guaranteeing that all simplification options are identified and applied. EFSA comments will be taken into consideration; however no legislation revision is foreseen in the next two years.

23. Endocrine disruption:

- update on guidance: progress and timelines**
- workshop: identification of case studies**

- **ED criteria: adoption and implementation (GD, impact on renewals) (proposed by EC)**
- **A.s. not already voted at date of application of the new ED criteria, evaluation will have to be updated: procedure, identification of a.s., tasks for EFSA and MS, timelines , harmonised information from MS to industry (proposed by FR)**

Timelines will be revised pending the decision by EC.

24. Aob

EFSA informed on the EUFORA Programme, as for this type of activities EFSA Advisory Forum will inform PSN members on this new activities and how to get involved.

The next PSN Meeting is envisaged to take place on 12-13 June 2018, for the time being no TC are foreseen in-between but might be organised on an ad-hoc basis if considered appropriate.

Next meeting: 12-13 June 2018