Network on Pesticide Steering meeting
Minutes of the 23rd meeting

Held on 12-13 June 2018, Parma

(Agreed on 11 July 2018)

Participants

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

Country	Name
Austria	Sonja ECKER
Belgium	Herman FONTIER
Czech Republic	Eva BOUSKOVA
Finland	Kaija KALLIO-MANNILA
France	Thierry MERCIER
Germany	Eva GOCLIK
Greece	Agathi CHARISTOU, Danae PITAROKILI
Ireland	Sadhbh O'DWYER
Italy	Pasquale CAVALLARO
Latvia	Līga BRENCE
Lithuania	Kristina VALIONIENE
Netherlands	Anko ARISSEN
Poland	Pawel STRUCIŃSKI
Slovenia	Ms Katja BIDOVEC Ms Milena KOPRIVNIKAR BOBEK
Spain	José Luis ALONSO-PRADOS
Sweden	Elisabeth DRYSELIUS
United Kingdom	John DALE

- **European Commission DG SANTE:**

Karin NIENSTEDT

Jérémy PINTE – participated in agenda points 5 and 6 via audio conference

- **European Chemicals Agency (ECHA):**

Nikolaos GEORGIADIS

- **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 (Angela SACCHI, Coordination Team)

Pesticides Unit (Chloé DE LENTDECKER, Coordination Team)

Pesticides Unit (Luc MOHIMONT, Deputy Head of Unit) - participated in agenda point 11

Pesticides Unit (Domenica AUTERI, Ecotoxicology Team) - participated in agenda point 12 and 15

Pesticides Unit (Stefania BARMAZ, Ecotoxicology Team) - participated in agenda point 12

Pesticides Unit (Maria ARENA, Ecotoxicology Team) - participated in agenda point 12

Pesticides Unit (Danièle COURT MARQUES, Mammalian toxicology Team) - participated in agenda point 13

Pesticides Unit (Frédérique ISTACE, Mammalian toxicology Team) - participated in agenda point 13

Pesticides Unit (Arianna CHIUSOLO, Mammalian toxicology Team) - participated in agenda point 13

DATA Unit (Bruno DUJARDIN) – participated in agenda point 13

Pesticides Unit (Andrea TERRON, Mammalian toxicology Team) - participated in agenda point 13

Pesticides Unit (Christopher LYTHGO, Environmental Fate & Behaviour Team) - participated in agenda point 14

Pesticides Unit (Anja FRIEL, Residues Team) - participated in agenda point 16

Legal & Assurance Services Unit (Simone GABBI) - participated in agenda point 4

Applications Desk Unit (Gabrielle KUBANSKI)

Applications Desk Unit (Sara DE BERARDIS)

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted with the following additional points for discussion:

- BE: discussing a common approach between MS for sharing or not the minutes of the peer review experts' meetings with the applicant directly after the meeting.
- FI: requested to organise a peer review experts' meeting for physical-chemistry section.

3. Practical guidance on preparing good quality dossiers and Assessment Reports

EFSA gave a presentation on the practical guidance on preparing good quality dossiers and Assessment Reports. The working group coordinated by EFSA on accordance check was set up in October 2017 as a follow-up from the Action plan for improving peer review process[1]. DE, EL, ES, FR, NL, PT, UK, SE and ECHA participated to the tele-conferences and commenting rounds. The guidance is intended to ensure that summary dossier and DAR/RAR are in accordance with data requirements and with applicable guidance documents and contain transparent and sufficiently detailed evaluations of studies; to give clear indications to applicants on the level of information needed in the summary dossier and to facilitate the RMS work as well as the peer review process by ensuring better quality of documents from the beginning of the process; to also give clear indications to RMS on what are essential elements for ensuring good quality DAR/RAR; to focus on key elements needed for initial risk assessment and consequent peer review; and to optimise EU resources by avoiding commenting and revising low quality documents. For this purpose, the working group prepared 3 documents, the practical guidance as such, the amended Document N3 and the completeness check checklists (for short-term and long-term use) listing the criteria that will be used to possibly reject a DAR/RAR. It has been noted that the practical guidance does not contain new proposals but only captures the current best practices proposing a more harmonised and compromised approach to support applicant and MSs.
Clarification on the following main topics has been given in the guidance: metabolites, impurities, literature search, analytical methods, non-submission of studies required by regulation, GAP table, MRL application under peer review, role of the RMS *vs* co-RMS, application art.4(7) and negligible exposure and risk envelope approach. The re-assessment of the old studies has been extensively discussed as it has been clarified in the guidance that all the studies have to be assessed and presented in modern study summaries. A template has been provided to standardise the reporting of studies.

EFSA proposed an implementation of the practical guidance and related documents in two phases. Based on the practical guidance, checklists were developed as a basis for conducting a completeness check: some points could be implemented already once agreed by MSs (short-term checklist) in order to improve the quality of the RAR/DAR. Once the practical guidance will be publicly available and considering an appropriate implementation period, the full checklist will be applicable (long-term checklist).

It has been mentioned that potential contradictions with existing guidance documents should be corrected (study waiving and document N3

[1] https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2017.EN-1349

(SANCO/10181/2013– rev. 3), re-assessment of old studies (SANCO/2012/11251 rev. 4).

In general, the PSN welcomed the practical guidance for improving the quality of the dossiers and RAR/DAR but several comments have been raised such as the literature search and the re-evaluation of all studies requesting considerable efforts from RMS.

EFSA explained that the old studies have to be re-assessed against guidelines and requirements currently in place, in order to conclude whether they are still valid and can thus be relied upon for endpoint setting. As example, EFSA clarified that the implementation of the new criteria on endocrine disruption would require updated summaries for most studies in the mammalian toxicology and ecotoxicology section submitted in the original dossier. It is considered the responsibility of the applicant to provide the re-evaluation of the studies in their renewal dossier. The RMS should present the assessment of the studies in the original DAR/RAR before the peer review starts in order to allow a proper commenting and discussion between peers.

EFSA clarified that the literature search is a legal requirement and should be presented in line with the EFSA Guidance2. The role of the RMS is to check whether the literature search has been performed properly and in line with the Guidance by the applicant and to present the outcome of the literature search in the relevant parts of the DAR/RAR. A template has been proposed for presenting the literature search in a transparent way in both the dossier and DAR/RAR.

A discussion took place regarding the NGO allegation that the RMS is copying the summaries provided by the applicants in the DAR/RAR. All agreed that a harmonised way of presenting study summaries and better clarifying in the DAR/RAR the parts that are indeed copied from the applicant's dossier but verified by the RMS, would increase transparency and is very important for the public perception. DE indicated that they are working on a statement to be included at the beginning of the study explaining the role of the RMS and that they will share with the PSN when ready. EFSA mentioned that this issue was also discussed by the working group and it was agreed that the RMS is the author of the RAR/DAR and therefore there is no need to distinguish between the parts verified and copied from the applicant and those drafted by the RMS. EFSA indicated that electronic dossier submission will be implemented in the future permitting to make clear what has been modified by the RMS.

EFSA will propose a short text explaining the role of the RMS and clarifying "copy/paste" issue, to be added in the introductory part of the Practical Guidance. This could also be added on the cover page of the Volume 1 and in the different chapters of Vol. 3 of the DAR/RAR.

Actions:

- MSs are invited to provide comments on the Practical Guidance by the 6th of July 2018.
- The Practical Guidance will also be distributed to industry associations for comments to be provided by the 6th of July 2018.

[2] https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2092

- Following the commenting round, the Practical Guidance will be amended where needed and presented to PAFF for note taking. In case conflicting comments are received, another teleconference with the WG might need to be organised.
- EFSA to propose a short text explaining the role of the RMS and clarifying "copy/paste" issue, to be added in the introductory part of the Practical Guidance. This could also be added to the cover page of the Volume 1 and in the different chapters of Vol. 3 of the DAR/RAR.

4. EFSA Policy on Independence

EFSA gave a presentation on the implementation of the new Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management[3] for assessing the declarations of interest (DoI) for experts participating to peer review meetings.

The participants to peer review meetings, including MS representatives, should complete a DOI which from 1st July 2018 will be subject to systematic screening by EFSA. The DOI screening approach is based on unconditional restrictions incompatible with the involvement in any EFSA scientific activity (i.e. current financial investments in "Industry" concerned with EFSA's outputs or industry employment) and qualified restrictions leading to "in or out" screening outcomes (i.e. managerial roles, membership of scientific advisory bodies, employment in organisations other than food/feed industries, occasional consultancy or research funding).

As far as the employees of national authorities participating in the peer review meetings coordinated by EFSA are concerned, the main expected sources of potential CoIs incompatible with membership would be identified in activities implying the performance of risk management functions (ongoing or in the past 2 years) or professional engagements benefiting individually «private entities» not in the public interest (ongoing or in the past 2 years).

Regarding the risk management functions, conflicts of interests are found for experts responsible for taking the risk management decisions or participating in a decision-making, or regulatory, group advising on risk management matters (e.g. members of national registration committees or PAFF committees) and the RM function overlaps with the subject matter of the EFSA scientific group.

Concerning the activities "not in the public interest", conflicts of interest are identified for activities benefiting directly or indirectly one or more specific food business operator(s) and overlapping with the remit of the EFSA scientific group with the exclusion of activities entrusted to the public institution via legislative mandate as well as education activities in the frame of the employment of the expert.

The 2 years cooling off periods are applicable both to overlapping risk management functions and activities not in the public interest. The ongoing civil service employment is considered to overrule past engagements with food industry, or other relevant private entities. Finally, if a dossier submitted by an

[3]http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

entity with which the expert had previously worked while in the private sector is discussed in the peer review meeting, the cooling off period applies and a conflict of interest is identified, resulting in the exclusion of the expert from the discussion of the relevant item.

It is mentioned that waivers are available in case of lack of suitable alternates for experts representing the RMS. The RMS is recommended to ensure that there is no conflict of interest already during the preparation of the RAR, e.g. asking EFSA to conduct a DoI screening of the RMS experts.

This approach will be implemented as of 1 July 2018 and the submission of the DOI will be requested before the invitation letter for the peer review experts' meetings can be sent.
It is recalled this approach is not applicable to PSN members but only to experts attending the peer review meetings.

Action:

- MSs are invited to contact EFSA as soon as a new expert will be involved in the peer review meetings in order to anticipate the DOI completion as an expert can only be invited to the peer review meeting if the DOI has been approved.

5. Alignment of EFSA pesticides peer review and ECHA CLH processes

The EC gave a presentation on alignment between CLP and peer review triggering the need for amendment of Regulation 844/2012.
It is recalled that classification is needed for decisions on active substances in the framework of the Regulation EC (No) 1107/2009 (cf low risk criteria and cut-off criteria in accordance with the provisions of Regulation (EC) No 1272/2008 ('CLP Regulation')). There is also a specific provision in the CLP regulation for the competent authorities of Member States to propose harmonised classification and labelling for active substances used in plant protection products and biocidal products (cf recital 52).

With the proposed amendment of Regulation 844/2012, the RMS will have the obligation to suggest classification in the renewal assessment report (RAR) (Article 11(e)) and to submit a CLH proposal to ECHA at the latest when submitting the RAR to EFSA (preferably by using the joint RAR/CLH report and submission to ECHA and EFSA at the same time to enhance coherence and ensure alignment). It was clarified that solutions are also needed for specific situations such as pending dossiers at ECHA/RAC, existing RAC opinions or existing CLH (Annex VI) or assessment of new information. As the amendment of Regulation 844/2012 has not been finalised, no detail has been given on these specific situations.

The main objectives are to allow EFSA to take account of the RAC opinion in its conclusions and to allow the EC as Risk Manager to take account the RAC opinion during decision making. For this purpose, the alignment of the timelines is essential.

The Draft regulation is still under inter-service-consultation within EC services and a presentation in the July 2018 PAFF meeting and in the next CARACAL (Nov

2018) is foreseen. A 4-week consultation with stakeholders via the EU website will also be launched (feedback mechanism). A transitional period for implementation of the amended regulation will be foreseen after note taking in PAFF.

EC will envisage a revision and merge of all existing GD related to drafting of DAR/RARs in one piece of guidance with collaboration by EFSA, ECHA and MSs.

EFSA presented the draft document "Alignment of EFSA pesticides peer review and ECHA CLH processes". The aim is to define the steps of the accordance check and public consultation phase and to propose corresponding timelines leading to a full alignment with the same data package. For this purpose, the following conditions are proposed:

i) use of the combined DAR/CLH template as the preferred option (available on https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_temp-assess-report_201211.pdf);
ii) parallel submission to ECHA/EFSA;
iii) common timelines for EFSA/ECHA accordance check;
iv) parallel public consultation.

Member States Competent Authorities (MSCAs) should keep both EFSA and ECHA informed on the progress/planned submission dates of DAR/RAR and corresponding CLH report.

The common timelines proposed for the accordance check were presented as follows:

- Accordance check on initial report in parallel by ECHA/EFSA: 10 weeks (still under discussion by ECHA);
- Revision of the report by the MSCA and resubmission: 5 weeks (proposed time period to be agreed with MSCAs);
- Re-evaluation of the resubmitted report in parallel by ECHA/EFSA: 3 weeks
- Revision of the report by the MSCA and resubmission (if needed): 2 weeks (proposed time period to be agreed with MSCAs).

Overall, the early communication of intentions by MSCAs together with submission of good quality assessment reports as well as good internal coordination between MSCAs (in particular where the national authority dealing with CLP and PPP is not the same) are considered key elements for a successful alignment. Several members of the PSN noted that as the authority for PPP at national level does not have the control on CLH report, coordination is clearly needed and thus, the existing timelines would be difficult to meet. In particular, more time would be needed to align both processes for addressing the comments sent to both national authorities. The necessity of flexibility was highlighted. This discussion should be handled by the PAFF committees.

AT raised the issue that they receive repeated requests from companies to submit CLH reports and to start the ECHA process 1 or 2 years in advance of the date of dossier submission in the framework of the PPP regulation (renewals and NAS). It was noted that for the time being applicants follow different approaches in different MSs as regards the timing of submission and this approach depends on the interest of the applicant. Overall, EFSA reiterated that efforts should be made to submit the documents in parallel to both authorities to allow full

alignment of both processes with parallel public consultation, thus avoiding having different data package. ECHA highlighted that in the event that the early submission of the CLH report is followed by the MSs, then additional considerations should be taken with regard to the potential new data. The use of the combined template is always recommended. As regards the need to propose new classification or amend/confirm the existing ones, EC clarified that a specific provision will be in the Regulation 844/2012 covering cases where there is a current entry in Annex VI of the CLP Regulation. Once the regulation is in place, it will be the obligation of the RMS to check the availability of any new data that would trigger potential amendment of the existing classification.

Action:

- MSs to provide written comments on the document "Alignment of EFSA pesticides peer review and ECHA CLH processes" by the 6th of July 2018.

6. Co-formulants

EC gave an update on unacceptable co-formulants in PPPs. A first presentation was given to PSN in October 2017 on this topic.

As background, EC recalled that the aim of the working group was to set up criteria for identification of unacceptable co-formulants (to be listed in Annex III of Regulation 1107/2009) and laid down in a new regulation. For populating the Annex III, two criteria were identified: co-formulants meeting the **cut-off criteria** (similar to active substances) set in existing regulations or co-formulants for which an **unacceptable risk** is concluded. The risk criterion for performing the assessment should be on a case-by-case basis, that of BPR, REACH or Regulation 1107/2009.
Two draft acts have been prepared (one setting rules for implementation of Art.27 Regulation 1107/2009 and one modifying Annex III) and were commented by GROW, ENV, MS and EFSA. DG ENV on behalf of DG SANTE gave a presentation to the members of the RIME (similar to PSN for REACh) last May 2018 and received a positive feedback.
It is mentioned that in the frame of REACh, the lowest tonnage substances are now registered (deadline was 31 May 2018) meaning that a complete data base is now available to identify co-formulants data.
The general scheme was presented. An unacceptable co-formulant can be identified by using the **existing information** (Restrictions, list of SVHC meeting criteria of Art.57 d), e), f) of REACH, harmonised classification, ED criteria, POP criteria, non-approved biocide a.s.). For the last case, it is indicated that a co-formulant might be a TP6 in biocides, the decision linked to its non-approval should thus be taken into consideration.
An unacceptable co-formulant can also be **newly specifically identified** by a MS or via screening of databases. The dossier is then checked by the Committee in charge of the risk management option analysis (RMOA) and concludes on the most appropriate process to address the concern identified. For example, in case of a concern related to CMR properties, the CLP Regulation (via CLH report) appears to be the most appropriate process; if the substance is not only used in PPP but also in detergent, then REACh could be the best option to cover all the different uses (via SeV/Annex XV). In the case the issue is specific to co-

formulant in a PPP, a risk assessment through Regulation 1107/2009 would be conducted. The envisaged peer review process is similar to a.s. peer review. The notifying MS would first assess the co-formulant (1 year), draft a co-formulant report, followed by an EFSA conclusion. If an unacceptable risk is identified, the co-formulant would be included in the Annex III. The ban could be total like for a carcinogenic compound classified category 1A or only some type of uses could be banned but not all (kind of restriction).
At any time point during the evaluation, it may be concluded that the concern is so specific that there is no added value to have EU assessment or EU decision and the best level to assess the concern would be at national level.
EC mentioned that an automatic listing of cut-off co-formulants (based on existing/future identifications or CLH report, Annex XV dossier (SVHC)) is foreseen. The evaluation should be performed according to 1/ REACh then 2/ Regulation 1107/2009 (peer-review by EFSA). Finally, a well-developed exchange between PPP and REACh/CLP MSCAs is necessary to properly set the identification and assessment of co-formulants as REACh MSCAs have access to the data.
A discussion on the revised drafts is foreseen (ISC, feedback mechanism, TBT) to be ended by the end of the summer and then, a stakeholders' consultation for 4 weeks will be launched (feedback mechanism). It was asked whether the draft act as such will be shared, however, EC will check internally as the draft acts can probably not be disclosed. It is indicated that at least a reference to the concept could be given e.g. cut-off criteria (similar to a.s.), use of existing knowledge.
The two acts would be finalised for presentation to PAFF in December 2018 or January /March 2019.
In the meantime, a guidance document for both procedural and risk assessment (referring to existing GDs) will be developed.
One member of the PSN mentioned that the procedure is based on hazard criteria and the studies on co-formulants might not be sufficient to address all the concern for consumer. RMS will have difficulties to perform the risk assessment as the data available would be less for the a.s. and thus the drafting of a robust conclusion might be difficult. EC replied that all the data available should be used (REACh registration dossiers – use as co-formulant *vs* other uses assessment).

7. Preparation of hearing with ECPA

EFSA presented to the PSN members the topics that will be discussed with ECPA:
- Implementation of action plan for improving peer review process,
- Practical Guidance on preparing good quality dossiers and assessment reports,
- Literature search
- Common assessment of metabolites arising from different a.s.

The PSN agreed on the discussion points.

8. ECPA hearing

ECPA gave a presentation on different topics:

- **Implementation of action plan for improving peer review process:**
    - ECPA would like to have access to the **FAQ document** (sanitised) as it would be a very useful document helping for the dossier preparation. EFSA replied that an internal discussion with MSs

would be needed to explore this possibility. Cfr Section 9 for agreed outcome.

- Regarding the **co-RMS involvement**, ECPA found very useful to have both opinions, they have experience of joint meetings and are of the opinion that it is very valuable.
- The possibility for RMS to have **pre-submission exchange with EFSA** is welcomed but ECPA would prefer to have EFSA directly involved.
- ECPA was seeking the preference of MS: do they prefer a **supplementary dossier submission or an updated stand-alone dossier submission**. Clarity on which option is the most effective for MSs is needed. The question was raised whether it would be possible for the applicant, who is not the applicant for the first approval, to indeed prepare a complete dossier. ECPA would try to establish access to the original dossier in order to submit a complete dossier but flexibility might be needed in case the applicant is different and then, a supplementary dossier could be envisaged. EFSA indicated that the old studies, that are part of the original dossier, did not need to be resubmitted in the renewal dossier. However, the assessment of old studies against current guidelines and requirements should be submitted through updated summary studies as part of the supplementary summary dossier. ECPA confirmed that an update of the summary studies of the old studies could indeed be provided. Cfr Section 9 for agreed outcome.
- ECPA would be keen to have the opportunity to suggest also **recurring issues and priorities for guidance.** ECPA would appreciate that the outcomes of the peer review expert meetings on general/recurring issues are reflected back into core documents.
- ECPA noticed that in general relatively few **MSs commented** on draft DAR/RAR and supported the effort to increase the involvement of MS experts. The transparency of experts meetings could be improved as the applicants are informed only at a later stage of the process on the experts' discussions. ECPA asked whether there is a possibility to share information right after the meeting.
- ECPA welcomed the extension of timelines to **3 weeks for commenting** on the assessment of additional information.
- The **involvement of applicant as hearing expert** during the experts' meetings has been discussed. EFSA mentioned that they will discuss internally how to handle the question of the applicant's participation to the meetings as all the stakeholders should have the opportunity to participate (e.g. also NGOs). Nevertheless, it has to be noted that it is not foreseen to remove the confidential data from the documents distributed for the expert meeting. EFSA clarified that for the time being, the RMS should propose to EFSA if they consider the participation of the applicant in part of the discussion would be helpful. The final decision to call the applicant during the experts' meeting is taken by the experts at the meeting. Cfr Section 9 for agreed outcome.
- ECPA highlighted that when it is reported in the EFSA conclusion 'the majority of the experts', this is actually the majority of the experts participating in the meeting. ECPA welcomed the reporting

of **divergent views** in the EFSA conclusion. EFSA indicated that all MSs' opinions are requested in the formal consultation on the draft EFSA Conclusion with all MSs meaning not only to experts attending the experts meetings.

- **Practical Guidance on preparing good quality dossiers and assessment reports**

ECPA supported the concept and found it helpful to clarify the task of the applicant and RMS. EFSA mentioned that a commenting round will be launched with industry associations on this document, closing on 06/07/2018.

- **Search and review of scientific peer-review literature:**

ECPA had in general a good experience regarding this requirement, the process works quite well in their opinion. However, EFSA raised the point that there are still many conclusions with a data gap related to this issue in the conclusion but it is specified that the data gap might also be related to a non-proper reporting of the information by the RMS. The template proposed in the practical guidance should improve this issue. EFSA mentioned that proper study summaries from result of literature search as detailed as that of a GLP study, even if considered only confirming the assessment, should be prepared by the applicant. This would be a good way to show to outside that literature search is also taken into consideration in the assessment. ECPA acknowledged the remark and will discuss internally how to address this issue for AIR IV and AIR V substances.

- **Additional topics**
  - Common metabolites: ECPA requested clarity on this issue that was already raised during the ECPA hearing in the PSN in October 2015. ECPA regrets that so far only one joint assessment for common metabolites took place (TDMs).
    EFSA mentioned that cooperation between the applicants having a.s. with common metabolites is needed. It would be valuable to have one data submission by one applicant to be submitted in the dossier for which renewal will take place first, followed by one evaluation performed by one RMS. EC took note of the comment and acknowledged that this approach would indeed save resources. ECPA would appreciate the possibility for joint submission. It has been mentioned that at least the same data set should be submitted in each single dossier and EFSA could launch the peer review process for substances sharing the same metabolites in parallel when timelines allow.
  - Future pre-submission meetings: The amendment of the General Food Law is introducing pre-submission meetings. ECPA asked whether a pilot together with RMS and EFSA would be acceptable. EFSA replied that the support to RMS is already offered, this is part of the Plan agreed by the PSN in 2017, already implemented, and not related to the EC proposal on the General Food Law. Following a request by the RMS, EFSA can participate via teleconference to pre-submission meetings in order to provide support to the RMS. Finally, MSs agreed that the pre-submission meetings would not be proposed on a routine basis for all substances and not to discuss

the whole dossier but focus on critical issues because of resource issues.

- Guidance document (GD) development and implementation: ECPA would appreciate to have a testing phase before the GD implementation to improve efficiency and offered to prepare case studies. EC mentioned that at least for the ED GD, MSs were requested to test it. EFSA indicated that because of the timeline, it would not be possible to test the GD before taken noted to avoid postponing the GD implementation. EFSA proposed to ECPA to prepare case studies on effect of drinking water treatment processes on stability of molecule. This could be a good example of applicant's contribution to be taken forward for preparation of GD on drinking water. ECPA took note of the request.

ECPA raised two additional questions on the status of alignment of EFSA/ECHA processes for CLH and on GD on negligible exposure. EC indicated that regarding the alignment of EFSA/ECHA timeline, an amendment of Regulation 844/2012 is under preparation and ECPA will have the possibility to comment (feedback mechanism). EFSA explained that classification issues will not be discussed at EFSA level when ECHA already concluded on classification. Concerning the GD on negligible exposure (draft of June 2015), EC mentioned that this GD has not been evolved because of resource limitations and discussions on criteria are still needed. However, it is recalled that from a legal point of view, negligible exposure should be assessed even if no GD is available.

9. Follow-up discussion of hearing with ECPA

- Regarding the FAQ document, EFSA proposed to share the questions/answers on general issues, for which no background documents would be needed. Every 3 months EFSA will publish a pdf version of the non-confidential version of the FAQ document on the EFSA website.
- For the question regarding the preference of MSs to receive a complete *vs* supplementary dossier, it was agreed that for the time being, the supplementary dossier submission would be kept. However, the assessment of old studies against current guidelines and requirements should be submitted through updated summaries of the studies submitted in the original dossier as part of the supplementary summary dossier.
  The problem for a generic company to access to the original dossier has been discussed. The same problem could occur when no task force is possible among several applicants applying for the renewal of the same substance. For the time being, only a case-by-case approach could be followed. However, MS would highly welcome that a common solution and a harmonised approach will be reached in future. EC will check internally. In case the new applicants have access to the studies, they should submit study summaries also for old studies. MSs should deal in the same way the question of realising old studies. It is apparent that MS handled the issue differently.
- Participation of applicant to experts' meeting
  In general, the PSN members were not in favour of the systematic participation of the applicant to experts' meeting and would prefer to keep the current option, to call them if clarification of a complex issue is

considered needed. The sharing of the minutes right after the experts' meeting with the applicant has been discussed and the PSN members did not see the benefit for doing this and anticipated an additional step to re-open the discussion. EFSA mentioned that the applicant already has the opportunity to submit additional data and that the reports of the experts' meetings are published at the end of the process. Indeed, the need of sanitisation of the reports before sharing with the applicant in case of several applicants would lead to additional work. It was concluded that the reports of the experts' meetings should not be shared with the applicant right after the meeting and this should be the approach followed by all RMSs in order to have a harmonised and fair approach to all applicants.

10. Guidance documents and methodological development

Discussions have already started with risk managers on the need to define specific protection goals for use in regulatory risk assessment, with a kick–off meeting between EFSA/EC last year. A challenge is that protection goals outlined in the legislation are often too general and broad to be directly applicable in particular for environmental risk assessment performed by EFSA.
For the moment the discussions are still in the initial phase and it is premature to provide any update. EFSA highlighted the need for a clearer separation of responsibilities in the development of guidance documents: i) risk assessment methodology to be conducted by risk assessors and ii) interpretation of the risk assessment outcomes in the decision-making process under risk managers' responsibility.
The EFSA Scientific Committee has adopted a guidance[4] which presents a framework for developing options for specific protection goals, in a three step approach, to make general protection goals operational for use in all areas of EFSA 's environmental risk assessment.
More specific dialogues with risk managers will soon re-commence to make progress with the definition of specific protection goals in ecotoxicology.

11. Update on the status of implementation of cumulative risk assessment

EFSA gave a brief overview of the work undertaken by the EFSA PPR Panel since 2007 on cumulative risk assessment to pesticides in cooperation with 4 external organisations (RIVM[5], ICPS[6], ANSES[7], DTU[8]). As an achievement and prerequisite for undertaking cumulative risk assessment, EFSA underlined that both methodologies for all steps of risk assessment and relevant data are available (such as occurrence data based on official monitoring results from national competent authorities and national food consumption surveys from various institutes in EU MSs as well active substance data retrieved from existing pesticides dossiers).
A phased implementation programme has been started in 2014, with a pilot phase taking place until 2018 with the cumulative risk assessment related to the

[4] EFSA Journal 2016;14(6):4499
[5] Dutch National Institute for Public Health and the Environment
[6] International Centre for Pesticides and Health Risk Prevention, Italy
[7] French Agency for Food, Environmental and Occupational Health & Safety
[8] Technical University of Denmark

thyroid and nervous system. Further cumulative risk assessment groups are going to be established between 2019 and 2023 covering additional organs, however priority should still be defined. 4 scientific outputs are envisaged to be produced covering the assessment of the nervous system: one on hazard identification and characterisation, two on cumulative exposure assessment (of which one produced by RIVM) and one on cumulative risk characterisation. In particular the reports aim to provide answer to the following questions:

i) what is the cumulative risk of neurochemical effects resulting from dietary exposure to pesticides in various countries and age groups, and

ii) what is the cumulative risk of functional alteration of the motor division of the nervous system resulting from dietary exposure to pesticides in various countries and age groups.

A meeting of the EC WG of experts on the Cumulative Exposure Assessment of pesticide residues took place on 15/06/2018 on the risk management aspects related to the assessment of cumulative exposure, with the aim, among others to confirm the intended level of protection. From 2019 onwards, the main objective will be to share knowledge with the national competent authorities. More specifically, as a long term objective it is aimed that MCRA becomes a fully compatible tool with EFSA's methodologies and data, and is used both by EFSA and national competent organisations for consistent and transparent regulatory assessments. In addition, to set up a work sharing process, EFSA intends to outsource the updates of the cumulative risk assessment groups to national bodies competent for the implementation of pesticide regulations. Finally, EFSA will consider how to incorporate cumulative risk assessments into the annual monitoring reports as from 2020.

12. Endocrine disruption:

- adoption Guidance, implementation and impact on renewals
- update on the "ED-criteria and implementation (draft Amendment to Regulation 844/2012)" by SANTE

EC and EFSA gave an update on the Guidance for the identification of endocrine Disruptors (ED GD) in the context of Regulation (EC) No 1107/2009. The pre-publication version of the ED GD[9] drafted by EFSA and ECHA staff, with support from JRC was published on 7 June 2018. This early version will be subject to a final editorial consistency check and typeset and the final version is scheduled to be published in the EFSA Journal in mid-July 2018. The scientific criteria for the determination of endocrine-disrupting properties are entered into force and are applicable from 10 November 2018 to new and on-going applications. Amendment to Reg. 844/2012 is under discussion aiming to introduce a "stop the clock" relevant only to ED data for pending applications.

A practical proposal for the implementation of the ED GD to the ongoing /up-coming evaluations was presented by EFSA. Different cases were identified and a procedure was proposed on how to address the new criteria in the assessment. No changes to the current process is needed for EFSA conclusions finalised before 10 Nov. 2018 (interim criteria apply), from 10 Nov. 2018 onwards

[9] EFSA Journal 2018;16(6):5311

applicants, MS and EFSA should address the new criteria. Further details on the practical implementation will be made available once the amendment to Reg. 844/2012 will be publically available.

The guidance document describes how to gather, evaluate and consider all relevant information for the assessment, conduct a mode of action (MoA) analysis, and apply a weight of evidence (WoE) approach, in order to establish whether the ED criteria are fulfilled, in a pragmatic way and outlining the studies needed for the assessment. It was clarified that in case draft EFSA conclusion is available and/or published before 10 Nov. 2018, then EC will decide case by case if pending applications are to be sent back to EFSA for assessment against the new criteria. Until 10 Nov 2018 EFSA conclusion needs to be based on the interim criteria, no change to this procedure is needed (since some years EFSA's Conclusions go beyond the interim criteria and assess also ED from a scientific point of view). It was also clarified that the confirmatory data related to ED will need to be assessed against the new ED criteria. This has already been captured in the approval regulation of a.s. in cases where further studies with regards the potential for ED effects should be submitted (i.e. pending the availability of the agreed guidelines).

All the parameters which are useful for the ED assessment, identified in each relevant and reliable study, should be reported in a tabular form to be provided by the applicant with the dossier. It is suggested that available information is reported in the Excel template provided with the ED guidance. FR indicated the workload and possible delays if the Excel tables should be filled in. EFSA noted that presenting the data using the Excel table, is largely beneficial and will help in building-up experience. The presentation in at least tabular format is prerequisite to perform the weight of evidence.

EC highlighted that Excel tables for pesticides and biocides containing the data and evaluations used in the screening for the impact assessment that accompanied the EC proposal are made available in CIRCABC. The data and the excel tables can be useful as a starting point for RMS evaluations, though were performed for the aim of the impact assessment. Nevertheless, RMS can use these excel tables with the already pre-filled information and perform quality check/add new end-points where needed.

13. Update on-going activities mammalian toxicology

13a. EC mandate for a scientific opinion on pesticides in foods for infants and young children

EFSA gave an update on the scientific opinion of PPR Panel on pesticides in foods for infants and young children. EC asked EFSA to perform a comprehensive evaluation on pesticides in food for infants and young children by reviewing the relevant opinions of the Scientific Committee for Food (SCF, 1997, 1998)[10] which set the default MRL for pesticides in food intended for infants and young children at 0.01 mg/kg, corresponding to the LOQ as precautionary principle. According to the specific terms of reference, EFSA was requested to cover in particular:

[10] Opinion of the Scientific Committee for Food on a maximum residue limit of 0.01 mg/kg for pesticides in food intended for infants and young children (19/09/1997) and a further advice on this opinion (04/06/1998).

- The assessment of the appropriateness of the toxicological reference values for infants and young children and of the approach to base the MRLs for pesticides for food for infants and young children on the ADI values (in this context the assessment of the short-term dietary risk should also be considered).
- The assessment of the contribution of other foods consumed by infants and young children and not covered by Regulation (EU) No 609/2013.
- The impact of a cumulative exposure to pesticides which share a common toxicological effect.
- The appropriateness of the residue definitions established under regulation (EC) No 396/2005 for infants and young children.

The scientific opinion on pesticides in foods for infants and young children has been adopted in May and is under pre-publication check. Communication to risk managers is ongoing.

13b. EFSA Guidance on dermal absorption

The new EFSA Guidance on dermal absorption (EFSA, 2017)[11] was taken note in the PAFF meeting (May 2018) and will be implemented as from 25th August. MS had raised concerns on the dismissed threshold (5%) to distinguish concentrate products from dilutions. Indeed, from the analysis of the experimental data collected in the ECPA and BfR datasets used for the revision of the guidance, it was evidenced that this threshold, established in the current guidance (EFSA PPR Panel, 2012)[12] without a clear explanation/scientific justification, is not correct due to an overlap between concentrations of the concentrate products and dilutions. MS agree on the assessment, however asked if a pragmatic threshold could be established in order to help them to distinguish the concentration status. The WG identified options to support EC and MS in order to address the issue on how to distinguish concentrate products from dilutions by setting an a.s. concentration cut-off.

EFSA representing the EC, is leading a project on the review and update of OECD documents on dermal absorption (Test Guidelines and Guidance Documents/Notes GN n.156, GD no.28 and possibly TG 418). MS were asked to nominate experts for the OECD Expert Group on Dermal Absorption that will participate to the revision of OECD documents on dermal absorption. **Deadline for the submission of nominations is 29th June. Nominations should be submitted by the MS Authority to the OECD National Coordinator in the respective MS.**

13c. Update on Developmental Neurotoxicity

EFSA gave an update on the past and on-going activities on Developmental Neurotoxicity (DNT).

According to the data requirements (Reg. (EU) 283/2013) there is no *a priori* requirement for pesticides or other chemicals to be tested for DNT effects prior to registration but this can be triggered by observations in other studies. Specifically when indicated by observations in other studies or the mode of

[11] EFSA Journal 2017;15(6):4873
[12] EFSA Journal 2012;10(4):2665

action of the test substance, supplementary studies or information may be required to provide information on the post-natal manifestation of effects such as developmental neurotoxicity.

Neurotoxicity studies in rodents shall provide sufficient data to evaluate the potential neurotoxicity of the active substance after single and repeated exposure. It was highlighted that the deficit in chemicals testing is due to a number of factors like systematic testing for DNT is not a mandatory requirement, standard guideline studies are not designed to inform on DNT mode of action. The interpretation of the results is very resource intensive.

The current DNT guidelines are entirely based on *in vivo* animal experiments (TG 426, TG 443). Sensitivity of the test varies, depending on the approach taken in setting the functional and behavioural tests leading to variability, therefore the implementation of the test was considered an issue.

EFSA has recommended alternative methods already in the PPR Panel Scientific Opinion (2014)[13] where an integrated in-vitro DNT testing battery was recommended by the PPR Panel in the assessment on acetamiprid and imidacloprid. In the external report (EFSA, 2015)[14] a testing battery was proposed able to explore all the key developmental process. An agreement was reached in the EFSA/OECD workshop (2017)[15] on the need for a draft framework for regulatory use of DNT data through an integrated approach to testing and assessment (IATA).

Currently there is EFSA procurement ongoing with overall goal to accelerate the development and use of *in-vitro* test methods for testing of chemicals for the potential to disrupt the development of the nervous system (it was noted that the system will be unlikely applicable for chemicals acting in DNT through an ED pathway). The first Phase will focus on the development of the test systems, generation of data using relevant chemicals for validation purposes, and the design and employment of data analysis tools to be finalised this year. The second Phase will include: the development of data interpretation and use guidance, and descriptions of possible application domains. EFSA is also leading the development of an OECD guidance (on behalf of EC) intended to provide a fit for purpose approach on DNT. An IATA approach is proposed as a backbone of the guidance (e.g. screening and prioritization, single chemical risk assessment). The guidance will consequently provide an analysis on how to integrate the individual assays, their interpretation and triggers and uncertainties analysis. Case studies will be developed and integrated. Additional projects can feed the experimental work (by Danish EPA, US EPA).

13d. In vitro comparative metabolism studies

According to the legal framework in place, the relevance of generating toxicity data in animal models with dissimilar metabolic profile to those found in humans shall be addressed, if such metabolic information is available, and taken into consideration for study design and risk assessment.

[13] EFSA Journal 2013;11(12):3471
[14] Literature review on in vitro and alternative Developmental Neurotoxicity (DNT) testing methods. EFSA supporting publication 2015:EN-778.
[15] Workshop on integrated approach for testing and assessment of developmental neurotoxicity. EFSA Supporting publication 2017:EN-1191.

The legislation also quotes that comparative *in vitro* metabolism studies shall be performed on animal species to be used in pivotal studies and on human material (microsomes or intact cell systems) in order to determine the relevance of the toxicological animal data and to guide in the interpretation of findings and in further definition of the testing strategy.

Key issues were identified over the last years and proposed to be discussed in a workshop on a pragmatic and scientifically sound way. The main issues identified comprise the identification of major and/or unique metabolites, the relevance of toxicological animal data and the human relevance. The liver enzyme induction was also considered as relevant as a key event thyroid disruption MOA (mode of action) was also considered relevant in this perspective.

A workshop on "*in vitro* comparative metabolism studies in Regulatory Pesticide Risk Assessment" will be organised by EFSA on 15-16 November 2018, in Parma. Pending on the outcome of the workshop an EFSA guidance on use and conduction of *in vitro* comparative metabolism studies is aimed to be developed.

The call for participation for MS experts will open in July.

13e. Update of EFSA Guidance Document on non-dietary exposure assessment

EFSA gave a short update on the EFSA Guidance Document on non-dietary exposure assessment. The current EFSA Guidance was published in 2014 and taken note by the PAFF in 2015 (with specific provisions). The need to update the Guidance with new data, correct errors etc was identified. EC mandated EFSA for an update of the GD in 2018-2021.

An open call for data will be launched in June 2018 in order to update the calculator. Additional input and new data to be considered include new greenhouse AOEM (BfR, 2015), BROWSE data/model, BROV WG data/model, seed treatment data, update of default values, update of risk mitigation measures, additional scenarios if new data are available. Update of risk mitigation measures should also reflect current practices in MSs (with clear reference to BE, FR, ES, DE).

The open call will ask for additional representative uses in EU (amateur use, seed treatment, post-harvest or indoor applications, bare soil or single plant applications), for additional risk mitigation measures (PPE/CPEs and related protection factors, technical equipment or packaging, new drift values and buffer zones), for refinement of re-entry scenarios, for update of the calculator (correction of errors, inclusion of more options for risk mitigation in one display), and will be more transparent and user-friendly.

Post meeting note: The call for data on non-dietary exposure assessment was launched on 18/06 (http://www.efsa.europa.eu/en/calls/data) and will be open until 18 December 2018.

14. Drinking water treatment process: roadmap forward

It is an approval requirement under Article 4 3.(b) of Regulation (EC) No 1107/2009 that a PPP shall not have immediate or delayed harmful effect on human health directly or through drinking water (taking into account substances resulting from water treatment). Applicants should submit information to fulfil this requirement. EFSA is evaluating the appropriateness of the submitted data,

leading to a possible identification of data gaps and issues not finalised in the EFSA conclusion. Where applicable, EFSA currently highlights concern regarding the potential formation of nitrosamine and chlorinated compounds, when ground- or surface water extracted for drinking water is exposed to water treatment processes. If the issue is not addressed in the EFSA conclusion, EC identifies confirmatory information for submission of further data as regards impact of water treatment processes, to be submitted when guidance will be available as currently there is no GD available on how to address this requirement. A working document has been drafted by UK in October 2014 and shared with PSN. To avoid any further pending decision on this topic EC suggest that the document developed by UK could be used as starting document to address this requirement. NL will verify internally on their capacities to contribute to this activity and will inform EFSA on the similar type of document available in NL (e.g. GD, national Guidelines), DE will also verify with their experts. FR pointed out how different methods are implemented in different MSs and how this could have an impact on the formation of all potential residues arising through these processes.

EFSA, UK, NL and ES will prepare a scoping paper based on the UK working document. The draft will be shared for commenting with all MS in September. A teleconference with PSN might be organised later this year to discuss the next steps.

Action:

- NL to send to EFSA any national Guidelines on drinking water treatment processes that could be useful for the drafting of the scoping paper.
- Other MSs to express their interest to participate in the drafting of the scoping paper, and inform EFSA by 13/07/2018.

15. Update on-going activities ecotoxicology

The general Meeting on recurring issues identified in Ecotoxicology will take place in the 2nd week of October 2018. The call for nominations will invite experts to identify topics for each MS/zonal assessment and valid for a discussion at EU level. EFSA encourage the participation of EC and to nominate one expert for each regulatory zone collecting general recurring issues.
EFSA presented an overview of the status of development activities in the ecotoxicology area:

- Update of Birds and Mammals GD: 1st WG Meeting is envisaged in October. The aim is to revise the existing guidance. The PPR Panel will work in parallel on a statement on bats. The main objective of the latter is to explore whether bats are covered by the existing risk assessment scheme in the B&M guidance.
- In 2019, it is also planned, if resources allow, to start working on the development of guidance document on the risk assessment for (i) non-target terrestrial plants (NTTPs)[16] and in-soil organisms[17].For both NTTPs

[16] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), Ockleford C, Adriaanse P, Berny P, Brock T, Duquesne S, Grilli S, Hernandez-Jerez AF, Bennekou SH, Klein M, Kuhl T, Laskowski R, Machera K, Pelkonen O, Pieper S, Stemmer M, Sundh I, Teodorovic I, Tiktak A, Topping CJ, Wolterink G, Craig P, de Jong F,

and in-soil organisms, Opinions of the PPR Panel were developed in the context of the self-task mandate on the update of the guidance documents on terrestrial ecotoxicology SANCO/10329/2002[18].

- Regarding the aquatic compartment, the opinion of the WG of PPR Panel on TK/TD effect models for regulatory risk assessment of pesticides for aquatic organisms is planned for adoption at the next PPR plenary meeting (27-28 June).
- In 2019, it is also planned to start the revision of the Aquatic Guidance Document (EFSA PPR Panel, 2013)[19]. In 2016, a corrigendum was foreseen to correct some issues identified in the document. However, this has been now turned into a revision which could take also into consideration the Opinion of the PPR Panel on sediment dwelling organisms (published in 2015) and the most recent on TKTD.
- Bee GD (EFSA, 2013)[20] is currently used for the risk assessment in order to reach a conclusion for the representative uses.
- The development of specific protection goals in the area of the environmental risk assessment, received the green light from EC (see PSN October 2017). EC informed that they will start working with MS risk managers. EFSA will be involved.

16. Update on-going activities on Guidance of the establishment of the residue definition to be used for dietary risk assessment

EFSA gave a presentation on the on-going activities on the Guidance of the establishment of the residue definition to be used for dietary risk assessment (EFSA, 2016)[21]. The Guidance was published in December 2016 as a need to embrace new approaches and the use of non-animal testing methods according to the new data requirements. (Q)SAR, TTC, Read-across concepts were already used in regulatory assessments though in non standardised way and this created the need for the development of guidance for harmonizing the use of these tools. The clarification on existing guidance (OECD No.63 & No.31) was raised.

The main features of the guidance include suggested systematic screening of metabolites for genotoxicity, the routine use of (Q)SAR, grouping & Read-across,

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Manachini B, Sousa P, Swarowsky K, Auteri D, Arena M and Rob S, 2017. Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms. EFSA Journal 2017;15(2):4690, 225 pp. doi:10.2903/j.efsa.2017.4690

[17] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2014. Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target terrestrial plants. EFSA Journal 2014;12(7):3800, 163 pp. doi: 10.2903/j.efsa.2014.3800

[18] European Commission (EC), 2002. Guidance document on terrestrial ecotoxicology under Council Directive 91/414/EEC (SANCO/10329/2002) revision 2, final. 1–39.

[19] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 268 pp. doi: 10.2903/j.efsa.2013.3290.

[20] EFSA (European Food Safety Authority), 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees). EFSA Journal 2013;11(7):3295, 268 pp., doi:10.2903/j.efsa.2013.3295

[21] EFSA Journal 2016;14(12):4549

the TTC - for combined exposure, the potency consideration before exclusion of minor metabolites, a guided strategy for selection of metabolites for testing (the most representatives), the use of alternative/mechanistic methods, relative potency factor and toxicological burden concept.

EC & EFSA proposed implementation plan for EFSA GD in PAFF-residues meeting in February 2018; EC collected MS feedback. The majority of MS who provided feedback support impact assessment on the approval process and on acceptance of CXL proposals, also involvement of ECPA to develop case studies. EFSA & EC both agree that international outreach is important aiming to amend existing international GD on RD (i.e. OECD GD), agree on updated international GD and only then adopt at EU level.

Regarding FAO/WHO activities a Work programme and funding related to harmonisation on pesticide residues definition for risk assessment is now available. FAO/WHO work programme includes harmonisation of residues from pesticides and veterinary drugs, particularly for dual use a.s. End of 2018 a joint JECFA/JMPR meeting will be held to discuss activities related to guidance on residue definition for RA. EFSA will present the GD on RD.

Revision of OECD Definition of Residue GD is initiated, the kick-off Writing Group meeting held on 8 June, where EFSA has been nominated to co-chair (on EC behalf). WG considers that robustness & usefulness of current GD for regulators & industry can be improved (e.g. increasing clarity; incorporating guidance on establishing toxicological relevance of metabolites). EFSA & EC consider that EFSA GD follows OECD principles, addresses toxicological relevance assessment for metabolites, and could hence be the basis for updating the OECD GD.

During the discussion the role of applicants against the implementation of the guidance was criticised. Though the applicant selects the part of the document to be used when favourable for the assessment, they claim that the implementation of the guidance will have a serious impact on the RD. It was clarified that the RD for monitoring will not change based on this guidance and an impact on the CXLs is not expected.

17. Update on EFSA Scientific Committee Guidance on nanotechnology with focus on nanopesticides chapter

EFSA gave an update 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 (SC). 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. The guidance is updating the 2011 guidance focusing on human health aspects by considering oral, dermal and inhalation exposure (Part I), while environmental aspects such as non-target organisms, ecotoxicology, fate and behaviour are planned to be covered in a second phase starting end 2018 (Part II). A public consultation of the draft Guidance took place in January-March 2018. During the public consultation more than 367 comments and letters were received from 29 interested parties. An overview of the comments received on the nanopesticides chapter was also presented. SC prepared an updated version of the guidance, taking into account the comments received and the updated guidance was adopted by the SC in May 2018. After its publication in the EFSA Journal in July a pilot phase for the implementation of the Guidance will follow comprising

testing with panels and units, hearings with stakeholders and info sessions. A technical report on the outcome of the consultation, presenting statistics on the comments received and providing a summarised description of how the comments were addressed in the finalisation of the document will be published as supporting publication alongside the Guidance.

18. Proposed agenda item by FR:

Application for double strands RNA, used as an insecticide on oilseed rape: exchange between MS and EFSA on experience and need to develop a specific methodology to assess such active substances.

FR has been recently contacted by an applicant for an experimental use permit containing a double strands RNA, used as an insecticide on oilseed rape. FR asked if EFSA or MS have an experience on this matter, if there is a need to develop a specific methodology to assess such an active substance. EFSA informed that discussions in the OECD Expert Group on RNAi-based pesticides are on-going and a Working document on Environmental Risks from the Application of dsRNA-Based Pesticides is currently under development. A seminar is planned to be organised by OECD in 2019 regarding the regulation of Externally Applied dsRNA-based Products for Management of Pests. DE requested that more MS should be involved in this Expert group.

19. AoB

- Update on PEST Committee: EFSA informed on the hearings, responses to the questions and presentations are available in the web of the European Parliament.
- FR raised an additional point related to Fluroxypyr (currently approved under Commission Implementing Regulation (EU) No 736/2011) on which confirmatory data were set under Regulation (EU) 2015/1040 as an outcome of the MRL Article 12 review (EFSA, 2013)[22]. FR received under the PPP MS/zonal assessment a new animal metabolism study. This study might highlight a concern for a metabolite that needs to be included in the RD. EFSA clarified that the procedure in the guidance SANCO/10328/2004– rev 8, case 4.3 should be followed.
- FI requested to organise a peer review experts' meeting on the physical-chemistry section. EFSA will ask MS to propose Phys-Chem discussion points via e-mail in September.
- EL presented to PSN members the topic of numbers of experts participating in TC in relation to a concrete a.s. case. EL had a mammalian toxicology Expert Meeting TC with only three participants (EFSA, RMS and Co-RMS). In this context and in case of controversial decisions, the conclusions reached by 'the majority' are questionable. EFSA highlighted that the written procedure on the draft EFSA conclusion aims at reflecting possible divergent views from MSs and in exceptional cases, based on

[22] EFSA (European Food Safety Authority), 2013. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for fluroxypyr according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(12):3495, 49 pp. doi: 10.2903/j.efsa.2013.3495

science based divergences an ad-hoc additional consultation could be organised.

The next PSN Meeting is envisaged to take place on 9-10 April 2019, a teleconference might be organised in-between if needed.