Network on Pesticide Steering
Minutes of the 19th meeting

Held on 27-28 October 2015, Parma

(Agreed on 8 January 2016)[1]

Participants

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

Country	**Name[2]**
Austria	Sonja ECKER
Belgium	Herman FONTIER
Czech Republic	Martin PROKOP
Denmark	Vibeke MØLLER
Estonia	Jan-Roland RAUKAS
Finland	Kaija KALLIO-MANNILA
France	Thierry MERCIER
Germany	Herbert KÖPP
Greece	Danae PITAROKILI
Hungary	Tamás GRIFF
Ireland	Aidan MOODY
Latvia	Liga BRENCE
Lithuania	Kristina VALIONIENE
Netherlands	Hanneke WESTLAND
Norway	Abdelkarim ABDELLAUE
Portugal	Bento DE CARVALHO
Slovakia	Marta GALUSOVA
Slovenia	Milena KOPRIVNIKAR BOBEK
Spain	José Luis ALONSO-PRADOS
Sweden	Katarina LUNDBERG
United Kingdom	Susy BRESCIA

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 them surname (John Smith) all throughout the document

- **Hearing Experts**

Agathi Charistou (for agenda point 5.1)

- **European Commission:**

Wolfgang REINERT (DG SANTE)

Jonas Nygren (ECHA)

- **EFSA:**

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

Pesticides Unit (Luc Mohimont, Deputy Head of Unit)

Pesticides Unit (Bénédicte Vagenende, Coordination Team)

Pesticides Unit (Stefania Barmaz, Coordination Team)

Pesticides Unit (Dimitra Kardassi, Coordination Team)

Pesticides Unit (Christopher Lythgo, Fate and Behaviour Team)

Pesticides Unit (Jean-Pierre Cugier, MRL Team), participated in agenda point 3.10

Pesticides Unit (Rachel Sharp, Ecotoxicology Team), participated in agenda point 4.3

Pesticides Unit (Mark Egsmose, Fate and Behaviour Team), participated in agenda point 5.2

Pesticides Unit (Anja Friel, Residues team), participated in agenda point 5.3

Pesticides Unit (Franz Streissl**,** PPR team), participated in agenda point 5.4

Pesticides Unit (Hermine Reich, MRL Team), participated in agenda point 9

- **Technical hearing (only for agenda point 6):**

Euros Jones (ECPA representative)

Ann Alix (ECPA representative)

Martyn Griffiths (ECPA representative)

1. Welcome and apologies for absence

The Chair welcomed the participants.

The Chair reported that the minutes of the meeting will be adopted by written procedure.

The Chair informed that in accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs) and the Decision of the Executive Director implementing this Policy, members of networks, peer review meetings, networking meetings and their alternates shall be invited to complete and submit an Annual Declaration of interest (ADoI). The responsibility for the appointment or nomination of representatives of the

Member State(s) or of its authorities rests exclusively at all times with their respective Member State(s).

EFSA invites members of Networks to complete and submit an ADoI for transparency reasons, without screening. EFSA shall publish the submitted ADoIs in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Specific Declaration of Interest (SDoI) or Oral Declaration of Interest (ODoI) are not requested.

2. Adoption of agenda

UK requested several additional points to be included in the AOB. However, the discussion was postponed for the next PSN meeting (see agenda point 10 for details). DE requested the withdrawal of the agenda point 4.2. The agenda was adopted with those changes.

3. Update on the peer review process

3.1 New ED decision on the peer review

The Chair informed the participants about the changes implemented by the Executive Director decision on pesticide risk assessment peer review (http://www.efsa.europa.eu/sites/default/files/eddecisionppr.pdf). In accordance with the ED decision the experts involved in the peer review meetings will be selected on the basis of the expertise and on the basis of the comments submitted. The ED decision includes the possibility to invite experts to cover additional expertise, where needed, in accordance with the selection procedure provided in the Decision of the Executive Director concerning the selection of external experts to assist EFSA with its scientific work.

Regarding the chairing of meetings, if the Chair is not part of EFSA staff, a full declaration of interest should be submitted. SE highlighted that Art. 9 of the ED decision is not in line with the Swedish National Law. EFSA reported that clarification from the legal unit is needed on this point and invited Sweden to contact the EFSA legal Unit to clarify the issue.

3.2 Alignment of the DAR and CLH report templates (report from the expert group)

SE reported that the working group on the alignment of the DAR and CLH templates organised two teleconferences (June and October 2015). Based on the teleconferences' discussions, KemI and ECHA prepared a proposal for a common template. This proposal compromises the necessity of CLP assessors to locate easily the information relevant for the classification and labelling and the needs of pesticides assessors to keep the structure and numbering of the DAR sections.

EFSA emphasised that the DAR should include a comparison with CLP criteria for all hazard classes and that, in order to increase efficiency, in the future parallel public consultations on the DAR and the CLH proposals can be planned. Ideally, the ECHA Risk Assessment Committee (RAC) opinion on the harmonised classification proposal should be available before the EFSA peer

review is finalised. ECHA highlighted that since the CLH process is longer than the EFSA peer review, RAC opinions may not be always available before the EFSA conclusion finalisation; there should be some flexibility.

It was highlighted that the common template will not solve the timing issues but it is important to ensure consolidated views, transparency and efficiency since the information needed for both processes, will be in one document. Additional coordination may be needed in the countries where the competent authorities for CLP and PPP are different. One member state indicated that the possibility for applicants to submit a draft proposal of the CLH report together with the pesticide dossier to the RMS should be considered. EFSA reported that the CLH report should be prepared by the RMS but that each RMS can decide how to organise the collection of the relevant information with the applicants. EC reported that the changes in the template should be reflected in the relevant OECD Guidance.

The draft template was agreed upon (for finalisation by a commenting round involving all MS). The Pesticide Steering Network asked EFSA and ECHA to consult the CLP/PPP competent authorities and the other relevant parties (e.g. RAC, CARACAL) and to report back on the consultation and the final agreed template to the respective DGs (DG ENVI, DG GROW, DG SANTE). EC agree with this approach. UK pointed out that despite the merging, there is no obligation to fill in the CLH part of Vol 1 of the DAR/RAR as this will depend on resources, priorities and the hazard properties of the substance. EFSA clarified that there is no legal obligation for the RMS to submit a proposal to ECHA for harmonised classification, but the DAR should always include a justified proposal on the classification of the active substance.

3.3 GAP table in DAR/RAR and GAP table clarifications with applicants

EFSA highlighted the importance of aligning the GAP in the list of endpoints with document D1 of the dossier. In case of unclarities in the GAPs, the RMS should seek clarifications with the applicant at a very early stage of the assessment. It was also emphasised that the assessment for all sections should be in line with the GAPs. Finally, the GAP tables should indicate if they are referring to GMOs or conventional crops.

3.4 EFSA support for the identification of candidates for substitution (proposed by AT)

AT requested to EFSA whether it would be possible to include in the EFSA conclusion a table summarising the key information on the candidates for substitution. EFSA reported that the key information is already available: the comparison with the criteria and a proposal is reported in Volume 1 of the assessment report. Where needed EFSA is setting open points for updating the Volume 1 so that at the end of the peer review, a clean and agreed Volume 1 is available to support the decision making. The current approach foresees that in the conclusion it is always highlighted if a substance is a POP, PBT or vPvB but not if a substance is a candidate for substitution. EFSA informed that an ECHA guidance on the identification of POP/PBT substances is available. This guidance document does not include clear criteria and therefore the EFSA conclusion does not cover this aspect. Further

clarifications from EC are needed. A discussion at PAFF level on EFSA involvement may be needed.

3.5 List of studies relied upon (proposed by DE)

DE asked a clarification concerning the list of studies relied upon which should be made publicly available for all active substances assessed and which should be available at the time of voting in PAFF (SANCO/12580/2012 – rev.3.1). This list is important for applications under Art.43. EFSA reported that EC is responsible for the publication of the list of studies relied upon. EC reported that the relevant Rapporteur Member States were previously asked to provide the lists but there was no interest at that time. A reminder (e.g., in PAFF) will be considered.

3.6 AIR 4 (proposed by AT)

AT requested clarifications on when the AIR 4 evaluation program should be available. A discussion took place regarding the low risk substances included in the AIR 4 list. The Chair questioned what would be the type of output for the low risk substances (EFSA conclusion, Technical Report ..). EC informed that this is not yet agreed with hierarchy, a similar process with peer review should be proposed, including the development of the list of endpoints (LoEPs), however, the idea is to save time in the consultation period and avoiding parts not important for the decision making. EFSA noted that in case of producing the LoEPs, the workload would be the same for EFSA/MSs. Some MSs (UK, SE, DE, DK, FR, NL) acknowledged that the assessment for low risk substances is often more challenging. A kind of peer review consultation was supported by most MSs. One MS noted that the LoEPs is important for national authorisations. UK informed that the AIR 4 list is intended to be voted in the December SCoPAFF meeting.

3.7 Clarifications regarding the amendment of approval conditions applications

EFSA requested that more information would be desirable on how to deal with applications for an amendment of the approval conditions. EC informed that the internal discussions (also with the COM's legal services) were not progressed. EFSA clarified that since there is no specific provision, such applications fall under Art. 7, and no other procedures than the ones for new active substances are applicable.

Action point:

- EFSA and EC to clarify the issue taking into account the MSs views. If relevant to discuss the issue in the next PSN meeting.

3.8 Assessment of common metabolites for sulfonylureas

SE made a proposal to SCoPAFF (8-9 October 2015) for the Commission to send EFSA a mandate to deliver an opinion on all metabolites by different sulfonyl urea compounds, including consolidated lists of endpoints for these metabolites. According to SE this would be the most efficient way to agree on a common set of endpoints to be used at product authorisation, and ensure equal level of protection from all sulfonyl urea compounds. It would also ensure an effective use of resources and assessment of applications. A similar exercise was successfully done a few years ago, for triazole

metabolites common to several different active substances, once all related parent compounds had passed the peer review stage. The background was presented. Triazine amine, triazine urea, amino pyrimidine, carbamoyl guanidine, and numerous other metabolites are formed by more than one sulfonyl urea herbicide. For one of these, triazine amine, EFSA has concluded that a genotoxic potential cannot be ruled out whereas several of the metabolites have the potential to leach to groundwater.
Currently endpoints available in dossiers for other sulfonyl urea compounds are not handled in a consistent way. Lately, EFSA requested during peer review of assessment reports that either the rapporteur member state or the applicant(s) present consolidated lists of certain endpoints for these metabolites and use these data for exposure and risk assessment, using the currently available EFSA conclusions on previously evaluated sulfonyl urea compounds. SE expressed their concern regarding this approach since it might lead to an unequal treatment of substances; endpoints potentially resulting in a more conservative assessment are used for substances that enter the peer review stage at a relatively late point in time, while substances for which an EFSA Conclusion already exists are not being re-opened to take account of the enlarged data set, including endpoints which potentially would have pushed the risk assessment in a more conservative direction.
For all sulfonyl urea active substances, including the ones currently under evaluation, SE suggests that each dossier is evaluated separately, without consideration of a broader data set available from other dossiers. This should be the standard approach, with the obvious exception regarding conclusions on the potential genotoxicity of triazine amine until conclusive data have been made available. At a later stage, when the consolidated list of endpoints has been made available, a review of the approvals of some or all sulfonyl urea compounds may be necessary, according to the provisions of Article 21 in Regulation (EC) No 1107/2009.
The Chair supported that EC should mandate EFSA to lead the assessment of common metabolites for sulfonylureas but the data call-in and risk assessment should be done by a MS authority (as the case for triazoles metabolites risk assessment). The standard peer review process from EFSA should follow. In the meantime, EFSA will continue following the current approach for the ongoing AIR III substances.

3.9 Peer-review meeting on general issues: feedback from the ecotoxicology meeting in September and proposal for a mammalian toxicology meeting in January 2016

EFSA informed that the feedback from the ecotoxicology experts' meeting on general issues held on September 2015 was very positive. The outcome of the discussions will be published as a technical report aiming at serving as a practical guidance document. No endorsement by SCoPAFF is foreseen. The Chair clarified that risk management decisions are not discussed in these meetings, only technical issues are discussed.

The MSs expressed appreciation for the ecotoxicology meeting and supported the organisation of expert meetings in other areas as well. EFSA informed that a dedicated toxicology meeting will be held in January 2016 (draft agenda proposals by mid-November). UK noted difficulties in

identifying the very specific technical issues avoiding interference with risk management decisions. UK and other MSs noted that the ecotoxicology meeting had discussed a procedural issue about the use of the still unnoted bee guidance. This was not considered acceptable. EFSA clarified the aim and points discussed at the meeting (see point 4.3). COM highlighted the possible linkage between risk management and risk assessment and requested more proactive communication on issues were the interference cannot be excluded. EFSA supported the communications on issues where relevant.

3.10 New templates and calculators for MRL applications

EFSA informed the Network about the new templates and calculators for MRL applications. The Excel spreadsheets calculators for MRL setting have been adopted in the SCoPAFF meeting of September 2015 and available to the MSs via EFSA Data Management System and have also been published on the COM website (http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines/index_en.htm).
EFSA informed that in the case of import tolerances (IT), the documentation related to the registration of the active substance (a.s.) in the exporting country shall be provided as well as an overview of the MRLs in place in the exporting country. If provided, the RMS/EMS can proceed with the assessment of the a.s. and therefore include the import tolerance evaluation in the Assessment Report (AR) and/or Evaluation Report (ER). In contrast, if evidence of the registration has not been submitted or if the a.s. is not yet registered in the exporting country, such documentations have to be requested and the evaluation of the IT should be excluded from the AR/ER on the active substance (possible change on residue definition and GAP table). One Member State commented that in the case of NAS the applicants are very keen to provide information on IT. The UK added that it disagreed with this approach and that it would start the evaluation of an IT even without the proof of authorisation in the exporting country, but would issue the MRL only after this proof had been obtained. It was agreed that it is up to the Member States to decide what to do in their own jurisdictions; but the EFSA assessment would only start when the information is available.

MRL calculation in food of plant origin:

EFSA highlighted that a harmonised approach for the selection of trials for MRL calculation in food of plant origin is proposed where specific requirements are applied. Also the proportionality concept is recommended assuming a linear relationship between application rates and residue levels. Therefore, residue data from trials conducted with variable application rates can be used for MRL calculations, assuming a scaling to the nominal application rate. The proportionality approach was endorsed by the Codex Alimentarius Commission at their 36th meeting in July 2013 and mentioned in the draft OECD guideline 509 on crop field trials. It is also recommended that values for MRL calculation should be independent and therefore, only one value has to be selected from each trial.

MRL calculation in food of animal origin:

Following the decision to use the Organisation for Economic Cooperation and Development (OECD) livestock dietary burden calculator EFSA proposed an

Excel calculator "*OECD Animal Intake & Feeding 2015_01.xls*" to perform the intake calculations according to the approach proposed in the OECD guidance document No 73. EFSA clarified that under the new data requirements, the animal dietary burdens have to be estimated considering the OECD feedstuff tables and OECD approaches presented in the guidance document on residue in livestock N°73. EFSA highlighted that the assessments conducted under "old" versus "new" data requirements, might result in significant different conclusions and different MRL proposals, since the animal diets considered for animal intakes calculations are significantly different (although the calculation approaches are quite similar). Also the number of animals, animal body weights and daily feed consumption are different for MRL calculations under the old and the new data requirements. The calculators are also needed for IT and animal burden calculations.

The OECD guidance is not listed in Regulation (EU) No 283/2013, as published later in July 2013, but there was a general agreement during the PSC of June 2014 meeting to consider this update for the assessment of the feeding studies. EFSA has developed an Excel spreadsheet calculator taking into account the changes and approaches proposed in the OECD documents.

Also according to the old data requirements residue intakes by animals should be expressed on the dry matter feed consumption basis (mg/kg DM) and the threshold value triggering the submission of a metabolism study is **0.1 mg/kg DM** whereas according to the new data requirements animal intakes have to be express on the body weight basis and the threshold intake for the submission of animal studies is **0.004 mg/kg bw/d**.

EFSA informed that a second dedicated PSN meeting on MRL procedures will take place most probably in the second semester of 2016 dealing among others with the transition from the interim to future process for the Art.12 review.

UK commented that the OECD guidance document No 73 has not been noted in the SCoPAFF and it is the UK understanding not to use the guidance document unless it is finally agreed. EFSA highlighted that this is an old discussion and that, in the Reg. (EU) No 283/2013, the trigger value of 0.004 mg/kg bw/day bw and the OECD feedstuff table is reported in the EU legislation under point 6 of the EU Notice 2013/C 95/01 where reference is made to the *OECD Guidance Document on Overview of Residue Chemistry Studies (as revised in 2009). Environment, Health and Safety Publications. Series on Testing and Assessment No. 64 and Series on Pesticides No. 32*.

EFSA commented that up to now, two different approaches were considered for the setting of the MRLs in animal products (based on the feedstuff table reported in the EU guideline 7031/VI/95 rev.4, under the old data requirements, or based on the feedstuff tables reported in the OECD Guidance Document, Series on pesticides No. 73). EFSA noted that the use of the new OECD feedstuff table is the only pragmatic approach and stressed the usefulness of the EFSA calculator in MRL setting.

4. Scientific issues

4.1 Aerobic mineralisation in surface water (proposed by AT)

AT asked clarifications regarding the new fate and behaviour data requirement: "Aerobic mineralisation in surface water". AT questioned which are the endpoints derived from the studies on mineralisation in surface water and what are they used for. Can or shall they be used a) for risk assessment, b) for triggering cut-off criteria (Persistence criterion), c) for identifying candidates for substitution? A defined, harmonised approach should be clear to all parties: EFSA, MS, EC, applicants. It was noted that according to the Regulation on new data requirements (Commission Regulation (EU) No 283/2013), the studies on aerobic mineralisation in surface water can be waived if the applicant shows that contamination of open water (freshwater, estuarine and marine) will not occur.

EFSA clarified that the OECD 309 and OECD 308 in relation to the hazard persistence cut off criteria apply, however in the last fate expert meeting it was discussed that the available guidance was not clear on what the relevant environmental conditions are for comparing to the cut off criteria.

EFSA confirmed that they will continue to include the valid end points from aerobic mineralisation in the assessment. EC will clarify further the issue with MSs.

Action point:

- Aerobic mineralisation in surface water to be further discussed between EC and MSs.
- Post meeting note: EFSA has become aware that ECHA has updated its guidance, which now indicates that the relevant environmental temperature for comparing half-lives to the PBT and vPvB cut offs, in water sediment and soil is 12°C. This is described on page 39 of the Guidance on information requirements and chemical safety assessment chapter R.11 Version 2.0: http://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf

4.2 Margin of exposure approach (proposed by DE) (Withdrawn)

4.3 Outcome of the ecotox experts' meeting on general issues

The ecotoxicology experts' meeting on general issues was held on 23 - 25 September 2015. EFSA presented the main outcomes of this meeting.

The scope of the meeting was to discuss recurring issues on new data requirements, new EFSA guidance documents and EFSA PPR opinions and on the renewals for the section on Ecotoxicology. The main subjects in the agenda were presented (i.e. risk assessment for bees, risk assessment for non-target organisms in light of the Guidance Document on protected uses, ECx vs NOEC in view of the new data requirement; the statistical power of the NOEC, evaluation and validity of old studies using new criteria, how to include/use literature in the risk assessment, establishing an appropriate long-term endpoints for the assessment of wild mammals). Other points

discussed were the determination of aquatic toxicity endpoints when the concentration was not maintained; algae toxicity studies (methodology for calculating the section by section CV); use of time-weighted average PECs (for exposure), further elaboration of the criteria in the new EFSA aquatic guidance document, soil organisms (factor of 2 to be applied for soil organism toxicity endpoints i.e. when 5% organic matter is used instead of 10% organic matter).

It was briefly explained the rationale behind the meeting namely the lack of risk assessment schemes for honeybees (i.e. covering chronic and larvae) in the currently agreed guidance document, the inconsistencies in approach to aspects of the DAR/RARs (i.e. re-evaluation of old studies, literature, application of new EFSA guidance documents and other updated methodologies), the mismatch between data requirements and guidance documents (ECx vs NOEC, calculation of the statistical power), the recurring experts' discussion points (mammal reproductive endpoint) and the clarification of parts of the the EFSA aquatic guidance.

EFSA explained that a Technical Report will be published soon as the main outcome of this meeting (publication expected November-December). Also the report from the meeting will be included as background document to the Technical Report. It was noted that there was a general agreement on the use of the Bee EFSA guidance document; however, several concerns were raised from MSs. It was highlighted that the current risk assessment scheme does not cover all aspects needed to address the risk to honeybees which are included in the new data requirements. For this reason, it is suggested that using the EFSA bee guidance document is the best method for making use of the data which is required.

Furthermore, a revision of the EFSA aquatic guidance document (correction and clarification) was recommended due to several inconsistencies being noted which has lead to different interpretations in the between the MSs assessment. Agreements were achieved on several technical issues that will ensure more consistency in the assessment of the active substances.

EC explained that the case of bees is not the only issue where new data requirements are applicable but no guidance document has been noted in the PAFF meeting. EC would prefer bilateral discussion with EFSA on controversial issues beforehand. Some MSs (UK, SI, IRL) disagreed with the use of EFSA bee guidance document until it is noted and endorsed. UK expressed concern on possible interference with procedural matters. DK is in favour of having a standalone document for the chronic risk assessment of bees and larvae.

EFSA noted that the EFSA Bee guidance document is able to cover all of the aspects requested by the new data requirements and, in the absence of an alternative risk assessment scheme, considers that the use of guidance is the best option. EFSA will continue to work on achieving a harmonised approach.

Action point:

- EC and EFSA will continue the discussion bilaterally.

5. Guidance documents

5.1 Presentation on the results and model availability from the BROWSE FP7 and next steps for OPEX guidance

Agathi Charistou on behalf of the the BROWSE Consortium presented the results of the BROWSE FP7 model for the assessment of non-dietary human exposure to plant protection products for bystanders, residents, operators & workers. The BROWSE project, supported by the EU 7th Framework Programme, has reviewed, improved and extended the models currently used in the risk assessment of plant protection products (PPPs) to evaluate the exposure of operators, workers, residents and bystanders.

The new and improved models for assessing exposure of operators, workers, residents & bystanders to pesticides, aiming to contribute to the implementation of Regulation 1107/2009 were explicitly presented. For operator exposure, the speaker noted that different options are provided for application scenarios (nozzle output, sprayer type, PPE, cabin use or not etc) and for mixing/loading scenarios. Several advantages of the model were highlighted: the mechanistic approach is not depending on exposure data, the model combines all relevant information (evidence from literature, experimental data, expert opinion), it can be easily refined with new evidence, and updated if new information/data becomes available. Also more options are provided to specify an exposure scenario and refine the exposure estimate compared to the currently available models, including exposure determinants and control measures.

For the worker re-entry exposure, different modules are combined into the software to estimate exposure from different exposure routes (oral, dermal, inhalation). The different options for TC factors and DFR values were also highlighted. For bystander/resident exposure, a wide range of options for refining the exposure are provided. Many input variables have options for using distributions (such as transfer coefficients, bodyweights, and breathing rates). Mitigation measures can also be taken into account. The use of probabilistic modelling was highlighted as advantage avoiding over-conservative approach of other models. Different case studies and comparisons with the EFSA calculator were presented. The BROWSE software is available in http://browseproject.eu/.

The Chair welcomed the project and acknowledged that data relating to resident/bystander exposure is limited. He also noted that the model could be used in a regulatory context. FR agreed and noted that the dataset for some scenarios in the EFSA Guidance Document is very small and supported the use of further refinements. MSs should discuss and reflect further how to apply this model. The Chair questioned if a PPR panel member should be involved to check the usability of the model for regulatory purposes. A statement or opinion could be produced on the general capacity of the model. DE agreed in exploring the possibility to use real data instead of assumptions.

EFSA informed that a call for data has been launched in this area. The main objective is to collect technical data and to re-analyse, where necessary, the

operator exposure assessments at EU level, focusing on exposure estimates. A lot of parameters are relevant to the BROWSE model.

Action point:

- MSs to inform EFSA should they want to participate in specific grants in the area of collecting data for operator exposure assessments at EU level.

5.2 Revision of priorities and status of the ToRs sent to EC

EC reported that they have revised the terms of reference (ToRs) of the 3 guidance documents agreed at the February PSN, and that their comments will be circulated shortly.

EFSA gave a presentation on the recent developments concerning the 'guidance on how aged sorption studies should be used for higher tier groundwater assessments'. It was reported that this guidance was prepared by FERA following a workshop held in York in April 2010. In April 2014, the PPR Panel was mandated by the Pesticide Steering Committee (now Pesticide Steering Network) for a scientific opinion on the guidance. The PPR Panel prepared a statement. It was decided to prepare a statement instead on an opinion since the Panel could not completely address all ToRs as the experimental data underlying the guidance were not available. As a follow up of the publication of the statement CRD (UK) consulted the authors of the draft guidance which prepared a discussion note on proposals for updating the guidance.

The need to keep the guidance on aged sorption studies in the priority list and the need for a PPR Panel opinion on an updated version of the same guidance was discussed. The PSN concluded that the guidance should be revised. Furthermore, EFSA will request ECPA to provide the underlying data-sets so the Panel can test the guidance using real data. The PSN concluded also that a PPR Panel opinion on the revised guidance is needed.

5.3 PSN involvement in the PPR guidance on residue definition

EFSA reported that the PPR Panel was mandated in December 2013 for drafting a Scientific Guidance Document on the establishment of the residue definition to be used for dietary risk assessment. The related Working Group is operative since January 2014. In June 2015 the PPR Panel agreed to an extension of deadline from December 2015 to June 2016 recognising the benefit of a 3rd case study and the possibility of longer public consultation period (8 instead of 6 weeks). In the meantime the PPR Panel was renewed and the WG composition was amended.

EFSA asked the PSN view on how to organise the consultation on this guidance at PSN level. The role of the PSN would be to comment on the applicability of the guidance. It was proposed that the PSN commenting will be during the public consultation and that the PSN comments will be incorporated in the commenting table as public comments. Ideally, a consolidated PSN document could be prepared, however, only two months are available between the public consultation and the adoption. Two options were discussed: organise a PSN meeting immediately after the public consultation or organise the PSN commenting early in the process. EFSA

concluded that the timelines for the PSN to provide feedback need to be further discussed. A proposal will be submitted after the meeting.

Action point:

- EFSA to prepare a proposal for consultation of the PSN on the draft GD

5.4 PSN involvement in the identification of protection goals for terrestrial organisms (NTTP, NTA, soil)

EFSA explained that general protection goals in the legislation need to be translated into specific protection goals. Specific protection goals options are available in the opinions on non target arthropods (NTA) and non target terrestrial plants (NTTP). The COM has in this case a coordination role. The PSN could have a co-ordinating role for liaising with risk managers in their member states.

6. Hearing with ECPA

ECPA gave a presentation outlining the general issues for discussion; each discussion point was addressed by the PSN as reported below.

6.1 General issues

Waivers for new data requirements

ECPA expressed concerns in relation to the EFSA position concerning the waivers for the new data requirements. In particular, ECPA reported that the EFSA position 'the argument that no agreed test method or guidance is available is also not considered a valid justification' is in contrast with the guidance SANCO/10181/2013-Rev 2.1 which states that waiving of data requirements for which test methods or guidance documents are not yet available is considered acceptable. EFSA explained that there is a misunderstanding on this point. EFSA considers the waiving is a risk management decision, when data are not available the risk assessment is considered as not finalised and this will be stated in the EFSA conclusion. In those cases, the assessment can then be re-opened when the test methods became available. It was highlighted that it is important to ensure that this is properly reflected in the EFSA conclusion.

Use of guidance before formal adoption

ECPA expressed concerns in relation to the use of guidance documents before formal adoption. The Guidance on the risk to bees and the Guidance document on aquatic risk assessment were referred to.

EFSA explained that in the case of the bee risk assessment for foliar uses, the EC mandate clearly indicated that the 'Scientific Opinion on the science behind the development of a Risk Assessment of Plant Protection Products on bees (*Apis mellifera*, Bombus spp. and solitary bees)' was to be used in the assessment. Considering that the Guidance on risk on bees was available and that the guidance implements the opinion it was decided to use the guidance. The UK and some other MS considered that guidance that has not been noted should not be used (see also points 3.9 and 4.3). ECPA reported that the guidance contains additional elements which are not covered by the opinion. EFSA replied that the additional elements are the protection goals.

Concerning the aquatic risk assessment guidance, EFSA explained that it is important that, when applicants decide to use a new guidance on a voluntary basis, this is done in full and not by incorporating only some elements.

Classification issues

Upon request, EFSA updated ECPA on the latest developments concerning the alignment of the DAR and the CLH report templates. The importance of an RMS-applicant dialogue and the possibility for applicant to prepare the CLH report to be submitted together with the dossiers to the RMS was discussed.

Analytical methods for active substances' renewal

ECPA expressed some concerns in relation to the data requirements related to the analytical pre-registration methods. ECPA reported that different requests are made depending on the active substance and section. EFSA clarified that, in order to avoid formalistic requests, the analytical methods are asked only when the experts consider that these are needed.

ECPA requested EFSA to clearly indicate in the data requirements where this information should be included. EFSA will include this in the agenda for the next consultation.

Assessment of common metabolites

In recent EFSA evaluations the issue of the assessment of metabolites common to different active substances was raised. According to ECPA, the approach followed by EFSA in this respect was not clear and consistent. ECPA reported that the applicants are available to work in task forces on this issue and in that case an agreement on the planning at Standing Committee level would be needed. The case of triazoles metabolites was reported as an example of approach.

EC will consider the possibility to have a mandate on this issue. EFSA highlighted the fact that it is utmost important to ensure that studies are assessed in the same way during the peer review; when additional studies with metabolites from previous assessments are available they cannot be ignored. Due to the complexity of the assessments, it is difficult to evaluate whether by considering additional studies the outcome of the assessment would be more adverse. For this reason, the assessment of data on common metabolites from previously assessed active substance is requested. EFSA reported that in reply to this kind of requests it is sufficient to use in the assessment the agreed endpoints from the published list of endpoints of the relevant conclusion. It was reported that there is still an access issue; it is difficult to mention studies for which the access is not granted.

Literature search requirements

It was reported that in some cases RMSs requested that the literature search should cover a period longer than 10 years; this is not in line with the legislation or with the EFSA guidance on submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009.

EFSA confirmed that the literature search on the active substance and its relevant metabolites should cover the scientific peer-reviewed open literature

published within the last 10 years before the date of submission of the dossier. There may be the case in which a relevant study is identified which was published before that period and in that case the study should be considered and submission of the study is requested. EFSA suggested that the applicants will further liaise with the RMSs on this point.

Ecotoxicological relevant end-points

ECPA referred to a recent case in which reference to agreements at the Pesticides Peer Review Expert Meeting 133 was made. ECPA emphasised that changes in the risk assessment should be agreed in Standing Committee to ensure implementation consistency.

EFSA indicated that recently a meeting on general ecotoxicology issues was held. The report of the meeting will be published soon to facilitate the implementation of the agreements. One PSN member highlighted that such meetings should focus on pure risk assessment issues and not on issues which interfere with risk management. EFSA agreed and announced that a similar meeting will be organised in the future for mammalian toxicology general issues.

Guidance documents development

ECPA requested more information on the planning of the PPR panel activities (next steps for completed opinions and list of priorities). EFSA informed ECPA that opinions under development will be discussed with the risk managers. Information on the guidance under development is available in the EFSA register of questions (now risk assessment workflow).

ECPA suggested that a testing phase is considered as part of guidance documents development process. The aim of the testing phase would be to assess and discuss the implications of the guidance and to calibrate and fine tune the guidance accordingly. The testing phase should be planned before the taking note of the guidance. EFSA reported that one of the tasks of the PSN is to ensure that guidance documents are fit for purpose. The current process foresees that first opinions are developed, afterwards specific protection goals are established and on this basis guidance documents are developed. Considering that at guidance document level there is not much flexibility being the level of protection established, the testing phase should occur at the opinion level.

ECPA informed that they are committed to provide data to refine trigger values and reduce complexity. EFSA welcomed this and informed that data submitted by ECPA will be used as much as possible.

6.2 Services to applicants

ECPA reported that so far there is not much experience in the use of the catalogue of services to applicants. ECPA sees high value in the direct dialogue with EFSA and expressed concerns in relation to the fact that there should be only dialogue with the RMS.

EFSA reported that its role is to peer review the risk assessment rather than to perform the risk assessment. In this connection, EFSA clarified that the dialogue should not be only with the RMS but through the RMS. When requests come from EFSA, the dialogue should be directly with EFSA. Upon

request, it was clarified that applicants can be informed on the experts' meetings points by the RMS and can provide the contact details of relevant experts to be contacted during the meeting in case clarifications are considered necessary. EFSA reported that the ED decision on the peer review meeting was recently published and that the participation of applicants/hearing experts in experts' meeting is not foreseen in the current procedure. The example of biocides' meetings in which applicants are invited to participate was given by ECPA.

6.3 January ECPA workshop

ECPA presented a proposal for a workshop to discuss on the use of higher tier data as part of the active substances evaluation process. The aim of the workshop would be to better understand the rationale behind acceptance and rejection of higher tier data starting from real cases (5 examples). The PSN members expressed some concerns in relation to the case studies. It was reported that the aim of the workshop should be to develop general rules and not to re-open previous cases. The examples proposed should be checked for their relevance and possibly reduced in number. Also, it was reported that higher tier data should not be confused with risk management measures. The role of the RMS in the discussion and the scope/structure and follow up of the workshop should be further discussed. EFSA suggested that the cases may be generic case studies with no reference to the substance. Also it may be useful to find more examples for each case.

ECPA clarified that the intention is not to re-open previous cases. The cases are a starting point to extract thematics and generic issues focusing away from substance specific matters. The final aim is to understand where higher tier studies are accepted/rejected to better understand what can be done to improve acceptance. The follow up of the workshop would be a report mainly for internal use, the format would still need to be clarified. The idea is to have a 1 day workshop, break out group sessions are not foreseen. ECPA reported that another workshop will be organised. In this case the focus would be on the bee related data requirements. EFSA and EC are invited but this should be seen more as an industry initiative. EFSA appreciated the initiative and agreed that a general discussion is needed but the timing is not suitable. Indeed, EFSA would be available to participate and present the technical report of the Pesticides Peer Review Expert Meeting 133 (Ecotoxicology-General meeting) which covers also this issue but this will not be published before December 2015. The best time for EFSA to participate would be end of January 2016. ECPA will discuss further internally on the way forward.

7. Services offered to applicants

This agenda point is covered by the agenda point 6.2.

8. Landscape and spatially explicit environmental risk assessments

EFSA had prepared a presentation regarding the approach from generic to landscape spatial explicit prospective environmental risk assessments.

The presentation was focused on the need for further reflecting the spatial variability within the EU in PPR Panel opinions, covering both exposure and effect assessments. Due to the time constrains the presentation was not given,

however EFSA informed that interested institutions could participate in non-regulatory Pilot Projects, co-financed by EFSA in the area of mapping environmental risks. A specific Charter has been developed and a draft will be distributed for comments. The projects will be financed under the EFSA grant scheme.

9. Outcome of the IESTI workshop, Geneva 06-09 September 2015

EFSA gave a short presentation. IESTI equations used for short-term dietary exposure assessment, developed 20 years ago and since 1999 IESTI equations were used by JMPR. In the EU acute risk assessment is part of MRL setting procedure since late 90ies. In 2004 the variability factor (VF) was lowered by JMPR, however, the lowering of the VF was not taken over in EU, thus the methodology was not fully harmonised and this was often the reason why CXLs were rejected. This discrepancy between EU and Codex approach (higher variability factors (more strict) in EU), creates trade problems. EFSA, in collaboration with RIVM took the initiative to foster discussion on international harmonisation on variability factors but also unit weights, large portions. Risk assessment is based on HR (highest residue found in supervised field trials) or STMR (supervised trials median residue, for bulked products), but MRL usually is significantly higher than HR/STMR. This is difficult to communicate. Enforcement bodies also need a tool to decide if a consignment analysed in pesticide monitoring should be taken from the market because of possible consumer health risks.

EFSA in collaboration with RIVM took the initiative to organise two events to discuss the possible options to revisit the IESTI equation, 7 September 2015: Stakeholder Meeting and 8/9 September 2015: Scientific Workshop (co-sponsored by FAO and WHO)

The purpose of the Scientific Workshop was to harmonise the methodology by discussing the individual parameters of the IESTI equation, taking into account the experience gained over 15 years. The change in level of conservatism introduced by the revised IESTI equations was not assessed by the meeting (risk management aspect) although examples were provided. Ca. 40 risk assessors of ca. 20 countries, including JMPR members participated. Several recommendations were prepared: the experts proposed a simplified version of the IESTI equation (unit weight no longer necessary); it was also proposed to replace the HR and STMR with the MRL in all cases of the IESTI equation for MRL setting. In the future, a list of commodities needs to be elaborated where the variability factor is not needed in the calculation of the short-term dietary intakes. The IESTI equation could be used for both MRL setting and enforcement. Other recommendations include the use of a conversion factor for risk assessment (if RD for enforcement and risk assessment are different), the P97.5 large portion value should be derived from the distribution of consumption values of dietary surveys expressed as g/kg body weight. If experts agree on the new approach, it would be necessary to develop a list of pre-defined processed commodities for which large portion data need to be derived; there is also the need to develop further guidance on how to derive a large portion data (e.g. the minimum numbers of eating events that would give a reliable estimate, how to fill in the gaps etc).

EFSA informed that EFSA event report of the meeting co-sponsored by FAO and WHO will be published by the end of 2015. The draft report was provided to JMPR 2015 meeting (10 to 24 September 2015), for its consideration. The report and the conclusions of JMPR may be on the agenda of CCPR 2016 (25 to 30 April 2016). A side event will be organised in the framework of this CCPR meeting, where CCPR members will be informed on the proposed amendment of the IESTI equations.

EFSA intends to further facilitate international discussions among all stakeholders and disseminate information as part of the next steps towards implementation of the revised methodology. Further strategies on the implementation of the revised IESTI equations will be developed following the discussions with risk management bodies, and the definition of the responsible bodies.

10. Any Other Business

UK raised several items under AOB. According to the UK there appear to be a number of areas where recently agreed positions (at the SCoPAFF or the Post Approval Issues group PAIG) are not being respected by all parties involved (especially EFSA), and they would be grateful if the Commission would consider clarifying/confirming these recently agreed positions with all MS and EFSA. The points raised involved fish metabolism data and fish feeding studies, validation data for methods of analysis, data to be assessed for the renewal of approval of active substances. However, since these points were not discussed in the PSN meeting due to time constraints, the UK was kindly asked to raise them again for the next PSN and thus officially include them in the agenda of the next meeting if they are still relevant. Two points raised on import tolerances and OECD feedstuff tables were discussed under agenda point 3.10.

Next meeting of the Pesticide Steering Network is planned to be held most likely in June 2016. If needed a TC will be planned after the physical meeting. MSs requested an annotated agenda to be sent in addition to the publicly available one.

NOTE: Documents distributed during the meeting, excluding confidential documents and preliminary documents for discussion only, are available upon request to pesticides.peerreview@efsa.europa.eu