Network on Pesticide Steering

Minutes of the 18th meeting

Held on 10.02.2015, Parma
(Agreed on 24 April 2015)

Participants

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

Country	Name	Country	Name
Austria	Sonja Ecker	Latvia	Vents Ezers
Belgium	Herman Fontier	Lithuania	Kristina Valioniene
Bulgaria	Iva Romanova	Malta	Joanne Borg Galea
Croatia	Gorana Peĉek	Norway	Abdelkarim Abdellaue
Czech Republic	Martin Prokop	The Netherlands	Hanneke Westland
Denmark	Vibeke Møller	Portugal	Bento De Carvalho
Estonia	Jan-Roland Raukas	Slovakia	Bronislava Škarbová
Finland	Kaija Kallio-Mannila	Slovenia	Milena Koprivnikar Bobek
France	Thierry Mercier	Spain	José Luis Alonso Prados
Germany	Herbert Köpp	Sweden	Katarina Lundberg
Greece	Danae Pitarokili	The United Kingdom	Susy Brescia
Hungary	Tamás Griff	The United Kingdom	Matthew Burns
Ireland	Aidan Moody		

- **European Commission and European Institutions:**
  - Wolfgang Reinert (DG SANTE)
  - Jani O. Honkanen (ECHA)

- **EFSA:**
  - Pesticides Unit (José V. Tarazona, Head of Unit, Chair)
  - Pesticides Unit (Luc Mohimont, Deputy Head of Unit)

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- REPRO Department (Juliane Kleiner, Head of Department a.i.), participated in agenda point 3
- Pesticides Unit (Bénédicte Vagenende, Coordination Team)
- Pesticides Unit (Dimitra Kardassi, Coordination Team)
- Applications Desk Unit (Tom Meyvis, APDESK Unit), participated in agenda point 5.3
- Pesticides Unit (Laszlo Bura, Physical and Chemical Properties Team), participated in agenda point 5.4
- Pesticides Unit (Christopher Lythgo, Fate and Behaviour Team), participated in agenda point 5.7
- Pesticides Unit (Rachel Sharp, Ecotoxicology Team), participated in agenda point 5.7
- Pesticides Unit (Mark Egsmose, Fate and Behaviour Team), participated in agenda point 5.7
- Pesticides Unit (Hermine Reich, MRL Team), participated in agenda point 5.9
- Pesticides Unit (Ragnor Pedersen, MRL Team), participated in agenda point 5.8

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted with the addition of two additional points under any other business from the chair of the meeting, and some additional points from the UK. The point raised by DE regarding the access of experts on the DMS was discussed under item 5.3. The point raised by the UK regarding the value of the kick-off teleconferences ((co)RMS, EC, EFSA) was discussed under item 5.1.

3. Introduction of Juliane Kleiner, new Director a.i. of the Department Scientific Evaluation of Regulated Products.

The new Head a.i. of the Department Scientific Evaluation of Regulated Products Juliane Kleiner addressed the members of the Network. Juliane Kleiner highlighted the scientific cooperation and sharing of expertise as key factors on the work of EFSA and of this network. She pointed out the significance of the electronic management of regulated products applications project which was introduced in the last PSN meeting and she highlighted the need for involvement of the members of this network on the adaptation of the electronic management system for pesticides applications.

4. Agreement of the minutes of previous Pesticide Steering Network

4.1 Minutes of the of the PSN XVII meeting held on 11 -12 November 2014:

The minutes of the PSN XVII meeting held on 11 -12 November 2014 were agreed taking into account the SE comments. The minutes have been published on the EFSA website (http://www.efsa.europa.eu/en/events/event/141111a.htm).

The chair informed that following the last PSN discussions, the divergence of views between RMS and EFSA are better reported in the main text of the EFSA Conclusion.

5. Topics for discussion

5.1 Work programme for the peer review, state of play

EFSA gave a short presentation on the status of the work programme for the peer review. The New active substance (NAS) Draft Assessment Report (DAR) and AIR III Renewal Assessment Report (RAR) submission tables are updated and available on DMS at the following link :

https://dms.efsa.europa.eu/otcs/livelink.exe?func=ll&objId=11142937&objAction=browse&viewType=1

The first AIR III RARs have been received and made available on DMS. Sanitisation with applicants are on-going, the MS consultation will be launched afterwards once the sanitisation agreed with applicants and in parallel with the public consultation. EFSA informed that for one NAS, Oxathiapiprolin, (RMS, IRL) the DAR has been received and the peer review assessment will run in parallel with the ECHA C&L.

EFSA introduced the way forward for the focussed peer review with regard to the kick-off teleconference (*co*)RMS/EC/EFSA. EFSA highlighted the challenges with regard to AIR III substances, timelines altogether 5 months following end of commenting period + clock stop (max 3 months). Compilation of the Reporting Tables and kick off teleconference, ca 6 weeks is taken from the 5 months so timelines are more tight than under AIR II procedure. Due to the tight timelines, Member States (MSs) were asked if they still consider the teleconferences as a useful tool and if this approach should be continued. EFSA clarified the relevant legal requirements (Art. 13(3) of Reg 844/2012; Art. 12(3) of Reg. 1107/2009) and expressed its view that the teleconference (TC) has been proven a useful tool to clear issues regarding the proposed expert consultation points, data requirements, and open points. EFSA presented some other options instead such as ad-hoc TCs or agreement through written procedure.

The UK questioned the usefulness of the teleconferences. They claimed that where there are significant disagreements on data requirements, open points and expert consultation points between the RMS and EFSA, EFSA is not open to compromise, but only to endorsement of the EFSA position. The UK explained that for renewals the UK disagreed with the numerous data requirements set by EFSA and highlighted the huge resource implications. Most of the MSs (i.e. DE, BE, NL, FR) were in favour of TC, they found it a useful step, having the chance to clearing issues. EFSA stressed that based on TC discussions, many open points are elucidated, clarifications are added to data requirements from respective expert colleagues after internal consultation. It was also noted that due to the strict deadlines for AIR III and NAS, the process cannot be delayed due to TC organisation and a practical solution should be sought while keeping deadlines.

EC found difficult to cope with the lengthy Reporting Tables in short deadlines, due mainly to resource constraints, and questioned the value of TC, commenting that it is EFSA's decision at the end. However, it was recognised by EC that most of the MSs find the TC a useful step in the process and they prefer to keep it. EC raised also the issue that some data

requirements identified in the Reporting Tables are not necessary from risk management point of view.

Following the discussions, the chair proposed to move to bilateral ((*co*)RMS/EFSA) instead of trilateral TC. EFSA and EC will agree on a mechanism to ensure that EC is kept informed and can provide comments where necessary.

Action point:

- EFSA and EC to take on the discussions on the mechanism for providing comments on the Reporting Tables. *Post-meeting note: EFSA made a proposal to EC to copy EC in all email messages to RMS (draft column 4 RT and minutes TC) to keep them informed on the discussions and provide further comments where necessary.*
- EFSA to discuss bilaterally with EC on the interpretation of data requirements.

5.2 Scientific literature search in the Assessment Reports

EFSA gave a presentation on the scientific literature search requirement on the Assessment Reports. Article 8(5) of Regulation (EC) No 1107/2009 requires that applicants provide "Scientific peer-reviewed open literature, [...], on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last ten years before the date of submission of the dossier..." as determined by EFSA. Literature search in Reg. (EU) No 844/2012 (AIR III) Article 7(1)(m), requires that "the supplementary dossier should contain summaries and results of scientific peer-reviewed open literature, as referred to in Article 8(5) of Reg. (EC) No 1107/2009".

The submission of scientific peer-reviewed open literature should be done in accordance to the EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA Journal 2011;9(2):2092). All Literature Review Reports should be incorporated in Doc K of the dossier (Section 9 or 11, in accordance with SANCO/10181/2013 – rev. 2.1). Relevant or unclearly relevant full papers are incorporated in the respective Doc K and summarised/assessed in Doc M. RMS should assess if the Doc K contains the Literature Review Reports covering scientific literature searches for data requirements in toxicology, residues in food/feed, environmental fate and ecotoxicology, if the Doc K contains full papers identified as relevant or of **unclear relevance** in the respective folders, and if Doc M contain summaries and assessment of relevant or unclearly relevant full papers. For the Literature Review Reports assessment RMS should check that relevance criteria are not too restrictive and have been correctly applied (no relevant papers excluded), check that appropriate data bases have been used for the search (not just a google search), check the scope and time frame of the search and the search strategy (covering a.s. and metabolites). Literature Review Reports summary and assessment should be incorporated in the AR before the references relied on list of each section. Summaries and assessment of relevant or unclearly relevant full papers should be under the corresponding sections of Vol 3. References of reliable papers should be listed under the list of studies relied on (Vol 2 and end of corresponding Vol 3 chapters).

Following a question from the UK, EFSA clarified that full papers identified as of unclear relevance should be provided in order to be able to check based on the full text if the paper is relevant for the risk assessment or not. Following a question from SE regarding the adequate number of reliable databases, EFSA agreed to provide a list of reliable databases since no exhaustive list is currently available in the Guidance.

Action point:

- EFSA to provide an exhaustive list of reliable databases for the Literature Review Reports assessment.

5.3 Update on EFSA Applications Desk

EFSA (APDESK Unit) gave a presentation on the first AIR III submissions. The new procedure on the alignment of the dispatch of the DAR and the RAR under the relevant legislations (Reg. (EC) 1107/2009 and Reg. (EC) 844/2012), was introduced. As a general principle the commenting period will begin upon publication of the sanitised DAR/RAR on the EFSA website and the deadline for submitting comments will be identical for Applicant, Member States and the Public. Making use of the new file exchange opportunities in DMS, a new DAR/RAR dispatch workflow was designed and presented. It was highlighted that accompanying official letters will be sent by fax and e-mail only and no longer by courier. The dispatch letter sent to Applicants will contain a link to the personal project on the DMS from where the DAR/RAR and accompanying documents can be downloaded. Before being able to access the project, Applicants will need to set their personal password following the link for password setting and user name, both also included in the dispatch letter. For security reasons the access to the projects will be limited in time (until the publication of the sanitised DAR/RAR). Applicants will also need to use the project to upload documents to be delivered to EFSA such as the sanitised DAR/RAR, the updated (supplementary) dossiers and an updated sanitised supplementary dossier.

The sanitisation of background documents follows the same procedure. The exchange of large documents between the Applicant and EFSA involves the same type of project on the DMS that was used at the time of the DAR/RAR dispatch and it will be used as exchange platform for these documents. Applicants will receive the link to the project and the credentials to reactivate their access when the Pesticides Unit invites them to sanitise the background documents to the EFSA Conclusion. As in the dispatch procedure, the project will be used as exchange platform during the sanitisation process. Also the naming convention for DAR/RAR was presented and special attention was given when several applicants are involved.

EFSA informed that new section on EFSA website will be published soon. Communication will be distributed to applicants for information. New dedicated document with work flows will follow.

Following question from DE, EFSA clarified that the DAR/RAR will be published only on DMS (no in CIRCA anymore), and MSs, Applicants will be alerted via email and not by automatic notification.

In this point DE requested that all information should be sent only to official contact points and not to all experts having access to DMS since most recipients are irrelevant. EFSA clarified that with the new DMS a more centralised approach is followed. It was recognised that not all the MSs have the same approach. However, most of the MSs agreed to a more restricted list of recipients in each MS in order to facilitate the coordination at national level. EFSA agreed to use as a starting point the list of nomination for the expert meetings and update the list with the MSs' requests. The changes in the list of recipients were made and agreed during the meeting.

The chair reminded the members to inform EFSA immediately in case a person cease working at national authority, in order to control the access to confidential information.

Action point:

- EFSA to present in its web pages the new procedure and release the stand-alone document on new DAR/RAR dispatch procedure with workflows.

5.4 EFSA-ECHA-MSs cooperation on Classification and labelling alignment

5.4.1. Substance ID under Reg. (EC) 1107/2009 and under CLP Regulation (presentations from EFSA and ECHA)

5.4.2. Sanitisation of the CLH reports

5.4.3 Alignment of CLH reports and the relevant parts of DARs

EFSA presented the Substance ID requirements under Reg. (EC) 1107/2009. The basic definitons were given such as substances, technical material (TC), technical concentrate (TK), significant impurities and relevant imurites. According to data requirements on the specification of purity of the active substance under Reg. (EC) 1107/2009, the minimum content in g/kg of pure active substance in the manufactured material used for production of plant protection products, shall be reported. A justification shall be provided for the minimum content proposed in the specification; this shall include a statistical analysis of the data on at least five representative batches. Additional supporting data may be provided to further justify the technical specification. The relative biological activity of each isomer, both in terms of efficacy and toxicity, shall be reported. If the active substance is a mixture of isomers, the ratio or the ratio range of the content of isomers shall be provided. If the active substance is manufactured as TK, the maximum content of each impurity shall be given, along with their content in the theoretical dry weight material.

It was highlighted that isomers that are not part of the ISO common name are considered as impurities. Regarding naming, the ISO common name is used as a basis for identification of the chemical active substance. The identity of the isomers of an a.s. composed by more isomers is already defined by its ISO common name. In some cases the ISO common name also defines the ratio of the isomers, however if it doesn't, it is very important to know what was the substance evaluated. Different examples were presented where the ISO common name defined or not the composition of isomers. Concerning the identity for the nomenclature of substances, in the evaluations by different organisations, different approaches may be used, for example in the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014).

The EFSA's approach used in the pesticides evaluation process was presented: If a substance is a mixture of diastereoisomers, and the ISO common name is not given to a certain ratio of these, any ratio might correspond to that name. Isomers that are not part of the ISO common name are considered as impurities. If the manufacturer of the a.s., however produces only a particular composition (a ratio, or a range), EFSA will mention it in the conclusion, or the company can apply for the modification of the ISO common name requesting to include a defined isomeric composition, or to define only one enantiomer/diastereomer as having that common name. The identity of the isomer profile in the ISO common name is very important and certain examples were presented where the ISO common name is not mentioning any ratio of isomers. Certain examples were given with different mixtures of active components with no ISO name (i.e. terpenoid blends, orange oil, azadirachtin, DDAC), the difficulties in the identification of the mixtures were stressed.

Certain examples with relevant impurities were given, however at or below the level presented, they were not expected to contribute significantly to the overall toxicity of the a.s. Other examples with different ratio of stereoisomers were given. It was highlighted that the ratio of the stereoisomers within an active substance consisting of a mixture of stereoisomers can change due to metabolism in organisms, to degradation in the environment or to processing and as a result of preferential degradation and/or conversion. As the stereoisomers can have very different endpoints, it is clear that the resulting mixture can have different properties compared to the original active substance.

ECHA followed with a presentation on the same subject. The idea of harmonised substance ID for active substances in CLH and PPP was introduced on the last PSN meeting. ECHA informed that the harmonised classification and labelling (CLH) report template has been put under revision and the new template will be published on the following months. The main changes to the previous versions were noted: the order of hazard classes follows the CLP regulation, study summaries can be annexed to the report (for example DAR). This increases flexibility for dossier submitters since study summaries drafted for DAR should normally be used as such. The sanitisation of CLH annex for new active substances (i.e. sulfoxaflor) containing part of the DAR needs to be done before public consultation which lasts 45 days (DAR sanitisation may not have taken place at this point). Also the Classification tables are improved – C&L table for the proposed C&L is in the same format as the Annex VI entry. It was noted that part of the study summaries in the DAR are also relevant for CLH and some elements may be considered to be common such as comparison with the CLP criteria; if the DAR contains C&L and the Substance ID (at least part of it). However, it was stressed that further discussion is needed mainly by RMSs, EFSA and ECHA.

The idea of the Substance ID check in the CLH process was presented. All substances submitted to the CLH process are subject to a substance ID check in ECHA. In most cases the substance ID of active substances in PPPs is set before the CLH process is initiated. The objectives of the substance ID check in CLH are to ensure that the substance definition in Annex VI follows the rules in Annex VI of CLP. The SID can be agreed in several step in the CLH process. Certain examples on the substance identity in CLH reports were presented. ECHA cheks the substance identity including substance name, EC number, CAS number, CLP Annex VI Index number, degree of purity, impurities, IUPAC name, molecular formula, structural formula, etc. In case of mixtures (i.e. terpenoid blend, a.s. in PPPs) separate entries for each component under CLP should be given, C&L of mixtures cannot be harmonised even if the mixture is an active substance in PPPs. Impurities are not usually included in the SID of a.s. in Annex VI, if the entry is based on pure substance then concentration of impurity should be taken into account in C&L of the substance placed on the market, however, there are some a.s. which have a maximum limit for an impurity defined in Annex VI.

ECHA highlighted that CLH intention and precheck are done months before the CLH report is drafted and submitted to ECHA. ECHA stressed the need for alignment in the step process, the CLH report to be submitted before DAR, the additional information to be submitted also to ECHA to be taken into account on the RAC opinion.

During the discussion which followed the presentation, the chair summarised that ideally RMS would consider the submission of the C&L dossier in parallel with the DAR. It was highlighted that in cases of same substance or same tox/ecotox data, the DAR will be practically used for C&L dossier. If different isomer, the classification may be different and another dossier should be submitted. ECHA agreed to follow the same approach on sanitisation issues. Following the presentations it was clear that the substance identity under Regulation (EC) No 1107/2009 may differ from the substance to be considered for harmonized C&L under the CLP. The implications of potential differences in the substance identity relevant for the classification and labelling should be further investigated. RMS were requested to consider the substance ID under both regulations, and the implications in terms of C&L, as early as possible within the process, contacting ECHA and EFSA if needed. The creation of an informal working group was proposed to further investigate common approach and support SID.

The UK appreciated the efforts for harmonising the template which will contribute to a huge savings of resources. Furthermore, the UK supported the proposal for the establishment of a working group to investigate the allignment of the hazard assessment sections in DAR/RAR and CLH reports in order the same content to be transferred in the CLH reports. EFSA and

ECHA will co-lead this working group. The UK, SV, DE and NO volunteered to participate. Should other MSs be interested they are invited to express their intention within two weeks.

Action point:

- EFSA to organise an informal working group to support SID.
- EFSA and ECHA to organise a working group for the alignment of hazard assessment sections in DAR/RAR and CLH reports. UK, SE, DE and NO to nominate the experts to participate to the working group. *Post-meeting note: FR informed EFSA after the meeting expressing their intrest to participate in this working group*

5.5 Templates for Mode of action from WHO/IPCS

The chair requested the agreement of MSs to communicate the templates for Mode of action from WHO/IPCS framework. The chair clarified that the toxicology experts in EFSA have found the templates useful. DE, UK supported the use of templates. No objections were raised. The chair informed that the templates will be published soon in the EFSA's website and that they could be found useful for applicants and for bilateral discussions with notifiers. EFSA will ask ECPA to disseminate the use of templates to its members.

Action point:

- EFSA to publish the Templates for Mode of action from WHO/IPCS on its website.

5.6 Update on Guidance Documents

EFSA gave an overview on needs and priorities survey regarding Guidance Documents. The proposed, planned, ongoing or completed activities regarding Guidance Documents were presented in a document comprising all activities. The updates from the previous version presented in last PSN meeting were highlighted.
References were included in the document with regard to:

- The SANCO guidance on the equivalence of technical materials (SANCO/10597/2003) and further activities in UK addressing the needs in physico-chemistry;
- The EFSA guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products approved in October 2014 and representing an essential step before further methodological developments related to the assessment of combined non-dietary exposure to pesticides;
- The roadmap of the EU commission on Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation (June 2014);
- The EFSA project regarding the gradual implementation of Cumulative Risk Assessment, following the methodological achievements of the PPR Panel and including the following activities and deliverables:
  1. 2015-2016: A 2-year Framework Partnership agreement between EFSA and RIVM aiming at performing cumulative exposure assessments of pesticides affecting the nervous and thyroid hormonal systems and at further developing the MCRA tool (accessibility, transparency and capacity). 2 External Scientific Reports will be delivered by RIVM regarding the cumulative exposure assessments.
  2. 2015-2016: EFSA scientific reports on cumulative exposure assessment using SAS for the same effects and with the same data as RIVM;

3. 2017: Delivery of EFSA scientific reports on cumulative risk assessment regarding effects on the nervous and thyroid hormonal systems;
4. 2016-2018: EFSA Scientific reports regarding the establishment/consolidation of CAGs of pesticides for the effects on the nervous system, liver, adrenals, eyes, thyroid, reproduction and development;

- The document "Estimation of animal intakes and HR, STMR and MRL calculations for products of animal origin" prepared by EFSA and proposed for discussion at the SCPAFF of February 2015;
- The updated version of the EFSA guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) published in July 2014 and the respective calculator tool;
- The Scientific Opinion of the PPR Panel on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products, adopted in February 2014 and published in March 2014;
- The Scientific Opinion of the PPR Panel addressing the state of the science on risk assessment of plant protection products for non-target terrestrial plants, adopted and published in July 2014;
- The Scientific Opinion of the PPR Panel addressing the state of the science on risk assessment of plant protection products for non-target arthropods, adopted in December 2014 and to be published in February 2015;
- The External Scientific Report delivered by FERA (UK) under a procurement contract 'Extensive literature search and review as preparatory work for the update of the Guidance of EFSA on the Risk Assessment for Birds and Mammals with regards to dermal and inhalation exposure', published in June 2014;
- The EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT5O values of active substances of plant protection products and transformation products of these active substances in soil, approved in April 2014;
- The External Scientific report delivered by VITO (BE) on the Software tool for calculating the predicted environmental concentrations of Plant Protection Products in soil, approved in June 2014. The tool is hosted by the Joint Research Centre;
- The EFSA guidance document on clustering and ranking of emissions of active substances and transformation products from protected crops (greenhouse and crops grown under cover) to relevant environmental compartments, approved in March 2014.

Progress regarding the update of the EFSA Guidance Document on the risk assessment for birds and mammals and regarding the evaluation of isomer mixtures are dealt with under point 5.7.

DK insisted on the need to complement the Guidance Document on birds and mammals with a calculator tool accessible for stakeholders.

AT asked the FOCUS surface water scenarios guidance long term revision (out of the scope of the repair action) to be included in the list. EFSA accepted.

EFSA informed the PSN that a formal consultation of the Commission and MSs on specific protection goals will be started in 2015 before the preparation of the EFSA guidance documents related to terrestrial ecotoxicology.

5.7 Terms of Reference for guidance development/update

- 5.7.1 FOCUS repair action

EFSA presented the terms of references (TORs) for the FOCUS repair action guidance. Austria, Sweden and the UK provided comments to EFSA distributed discussion note dated 7 November 2014. According to the FOCUS "repair action" a 20 year assessment period instead of the current 16 months assessment period will be introduced into all FOCUS

surface water scenarios (both runoff and drainage). Most UK comments have been taken on board, a separate document with EFSA responses to BE and the UK comments on the draft ToRs for the FOCUSsw repair action was produced and made available to the PSN before the meeting. BE questioned if NL could share their national approach on calculating concentrations for a.s. and metabolites at the point of abstraction of surface water for drinking water. NL accepted to share its approach in expert meeting and the chair proposed to make available the NL methodology through the DMS dedicated folder. The TORs were accepted with no amendments (the final document is included into the Annex of these minutes).

Action point:

- NL to upload the NL methodology onto DMS.
- EFSA to send the ToRs to EC. EC should consider to mandate EFSA.

- 5.7.2 Isomers

EFSA presented the terms of references (TORs) for preparing guidance of EFSA on completing risk assessments for active substances of plant protection products that have isomers and for transformation products of any active substances where these transformation products may have isomers. Comments were received by the UK and BE and the draft TORs were amended as appropriate.

Based on the previous discussions, EFSA proposed to develop a guidance that addresses appropriate practice for completing risk assessments for active substances of plant protection products that have isomers and for transformation products of any active substances where these transformation products may have isomers. The main focus of the guidance will be stereoisomers because of the additional analytical challenges characterising this class of isomers. However the guidance will also cover structural isomers. The guidance will aim to deliver the same level of confidence in the risk characterisation when there are isomer issues, as for a risk characterisation where there are no isomer issues.

It was stressed that the Guidance should among other focus on approaches, study designs and test organism selection, when risk characterisations indicate that toxicological or ecotoxicological reference values need to be determined for individual isomers or isomer compositions that differ from those in the technical substance originally tested.

The UK questioned if for this TOR risk managers are to be consulted but EFSA clarified that a consultation is not necessary for this kind of document. Of course a public consultation on a completed draft document is envisaged to take place afterwards. It was stressed that there is no need for a discussion on protection goals, as the goal is to deliver the same level of confidence as for the risk characterisation when there are non isomer issues.

The TORs were accepted with some editorial modifications (the final document is included in the Annex of these minutes).

Action point:

- EFSA to send the ToRs to EC. EC should consider to mandate EFSA.

- 5.7.3 GD on Birds and Mammals

EFSA presented the proposal for Terms of References for updating the EFSA Guidance on pesticides risk assessment for Birds and Mammals. Comments were received from UK, SV, BE. The scope is to amend the EFSA guidance 'Risk Assessment for Birds and Mammals' (EFSA, 2009)[1]. It is considered appropriate to update the risk assessment methodology of EFSA (2009) taking account of the new legislative framework and the recent scientific research and developments. EFSA clarified that the EFSA guidance for Birds and Mammals was one of the first guidance produced by EFSA and needs to get updated and be more user friendly, using the feedback from the peer-review exert meetings. The new guidance should provide clarifications on the current methodology where needed.
AT requested the involvement of national experts at early stage. The chair confirmed the involvement of national experts and clarified the role of the PSN according to the new mandate. SV and DN asked EFSA to consider the possibility of further harmonisation of higher tier risk assessment within EU regulatory zones and the possibility of providing a calculator tool to accompany the updated guidance document.

The TORs were accepted with some editorial clarifications and the updated TORs reflect the discussions (the final document is included in the Annex of these minutes).

Action point:

- EFSA to send the ToRs to EC. EC should consider to mandate EFSA.

5.8 Assessment of endocrine disruption in EFSA conclusions, state of play

EFSA presented the state of play with regard to the assessment of endocrine disruption in EFSA Conclusions as a follow up from the November PSN meeting.

Based on the comments of MSs and EC, and on experience gained, EFSA has refined its communication approach in the Conclusions; no longer make reference to the 'lack of agreed scientific criteria' to avoid confusion with the hazard assessment with regard to the current interim criteria. As a result four Conclusions (2,4-D, Lambda-cyhalothrin, Pyridate, Sulfoxaflor) will be re-published with editorial clarifications not affecting the scientific assessment.

Regarding the second interim criteria, an agreed scientific approach is currently not available for interpretation of the 'may be' in the second interim criteria. The second interim criteria states : "In addition, substances such as those that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, **may be** considered to have such endocrine disrupting properties." EFSA is providing scientific support to EC regarding their decision making for the consideration of these interim criteria.

EFSA also informed that the call for proposals on the scientific support for the interpretation of mammalian toxicology and ecotoxicology data on potential endocrine disrupting effects was unsuccessful due to lack of applications. Another approach should be further considered.

[1] EFSA (European Food Safety Authority), 2009. Guidance Document on Risk Assessment for Birds and Mammals on request of EFSA. EFSA Journal 2009; 7(12):1438[358 pp.]. doi:10.2903/j.efsa.2009.1438.

5.9 Workshops on acute dietary exposure (EFSA/WHO/FAO/RIVM) and soil risk assessment (EFSA/ECHA)

- Workshop on acute dietary exposure (EFSA/WHO/FAO/RIVM)

EFSA informed that a workshop will be organised on acute dietary exposure estimations by EFSA/WHO/FAO/RIVM. It was flagged the need to discuss the short term exposure and especially the so-called IESTI (International Estimated Short-Term Intake) equation. It was stressed that the variability factors used in the IESTI equation are different at European and Codex level therefore alignment might be needed. The IESTI equation is based on HR values but the MRL can be more than two times higher than HR so the IESTI equation may not guarantee the consumer protection in certain cases. The issue should be re-discussed in a workshop which is tentatively agreed to be held back-to-back with the JMPR in September 2015. A limited number of experts will be invited for a three-days event, with an additional day open to stakeholders. A Technical Report with recommendations is foreseen to be produced. Further details on the nomination of experts will be communicated at later stage.

- Workshop on soil risk assessment (EFSA/ECHA)

The chair informed that ECHA in partnership with EFSA, will hold a Topical Scientific Workshop on Soil Risk Assessment with academics, regulators, representatives of industry, and other stakeholders. The aim of the workshop is to develop new or improved scientific approaches in support of European regulations in this area. The Scientific Workshop on Soil Risk Assessment is planned to be held on 7-8 October 2015 at ECHA. The primary objective of this workshop is to review the state of the art in soil risk assessment with a view to developing updated scientifically-sound principles and approaches for assessing ecological risks of chemical substances, including pesticides and biocides, which are released to/or reach soil. The workshop also provides a platform for academia and regulators to address how the main long-term challenges from the regulatory perspective can be reflected and employed in the current and future research topics on soil risk assessment. The discussions will be reinforced by information on recent developments and on risk assessment methodologies applied in chemicals management both within and outside the European Union.

Participation in the workshop will be by invitation only following an open call for expressions of interest. The first announcement with an Expression of Interest will be published in early 2015. The call for experts will be launching by both agencies simultaneously.

Reflecting the current state of science on terrestrial and soil ecotoxicology, three groups will deal with the following themes of the workshop:

•Problem definition and conceptual model for soil risk assessment
•Environmental exposure and fate assessment
•Effect assessment

Action point:

- EFSA and ECHA to launch the call for experts.

5.10 ECPA request for a technical discussion on higher tier data

The chair informed the members of the Network that ECPA had asked for a technical discussion on higher tier data. The chair presented the different options while stressed the limitations for EFSA to involve industry experts in EFSA meetings. One option would be a Technical Workshop organised by ECPA with the participation of EFSA and MSs experts.

Another option might be ECPA to make a presentation in one of the expert meetings (participation as hearing experts) and a discussion to follow only between EFSA and MSs. There was general agreement regarding the convenience for including MS risk assessors and to avoid substances under discussion. The MSs requested more information on specific questions raised by ECPA; this would facilitate the nomination of appropriate experts in the above discussions and would enhance clarity on the aims and expected outcomes.

Action point:

- EFSA to further clarify the issue with ECPA and to specify questions on higher tier data.

5.11 Capacity building and specialised training activities

The chair informed the members of the Network on the possibility to attend specialised training activities organised by EFSA. A workshop on QSAR models has been organised recently for EFSA experts and a similar initiative could be undertaken for MSs experts. Should MSs be interested, the workshop could be organised back-to-back with a Peer Review meeting or alternatively a dedicated workshop could be fixed. Following a question from the UK, the chair clarified that the software used in QSAR models is free of charge. It was agreed that the agenda and other information on the workshop will be uploaded onto DMS and a call of interest will follow. Based on interest EFSA will take care of the organisation.

Action point:

- EFSA to make available the information on the workshop onto DMS. EFSA to launch the call of interest.

6. AOB

6.1 The chair informed that ECPA requested access to the agenda and meeting documents of this meeting. As agreed in the previous PSN meeting, access to documents could be provided only after the meeting (and not before).The minutes would indicate that documents, excluding confidential documents and preliminary documents for discussion, distributed during the meeting are available under requests. ECPA also asked their participation in part of this meeting, however this request was rejected.

The discussion was focused on possible cooperation with ECPA on defining the EFSA services addressed to applicants. Once the catalogues with the centralised services of EFSA is published, the elements relevant for pesticide applicants it will be discussed first with MSs. A possible involvement of industry is not excluded should it be beneficial (possible hearing of associations could be introduced in part of the meeting/ this could be concluded on following PSN meeting). The MSs appreciated the EFSA proposal for involving the PSN.

6.2 The chair informed that EFSA has received from a third party a request to access to all monitoring data for chemical and microbiological hazards, as of 2011 submitted to EFSA by MSs. The request is focused on raw data (not aggregated). EFSA will consult with MSs which data should be considered confidential. Some MSs have published the monitoring data in their website, whereas other MSs agree only to provide aggregated data, in addition some fields in their databases are considered confidential by some MS. For the future, in line with the policy for openness and transparency as well as for increasing efficiency, the non-confidential information could be made publically available through a dedicated IT tool. The

chair requested the network member to inform their contact points on this issue and foressen consultation from ESFA.

6.3 The number of PSN meetings/ year was discussed. The members would appreciate a larger space between meetings in case two meetings/year are scheduled. Some meetings can be replaced by teleconferences especially when specific subjects should be urgently discussed. Although the decision depends on the needs and elements to be discussed, consensus was reached to organise a regular meeting every 8 months supported by dedicated teleconferences (of 2-3 hours) between the meetings. No consensus was reached regarding the preference for the organisation of one-day meetings(two 1/2 days or a full day meeting) thus both approaches will alternate.

6.4 The UK requested a discussion on skin irritation studies. The UK informed the Network that they still receive *in vivo* skin irritation studies (for actives and products) which are illegal as animal tests should be regarded as the last resort especially when fully validated and stand-alone *in vitro* studies suitable for C&L and risk assessment purposes are available. The UK will inform applicants through their website and no data protection will be granted to unnecessary in vivo studies.

6.5 A question was raised by the UK with regards all the old DARs/RARs that are currently on CIRCA BC. If DARs/RARs under evaluation are only placed on the EFSA DMS, we might end up with old DARs/RARs on CIRCABC and newer DARs/RARs on EFSA DMS. Ideally, there should be only one point of access. The chair informed that the request will be further discussed with EC bilaterally.

Action point:

- EFSA and EC to discuss the issue.

7. Next meeting

Next meeting of the Pesticide Steering Network will be held on 27-28 October (most probably two 1/2 days depending on the agenda items).

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

Enclosed: Annex

- Proposal for Terms of References for “repair action” of the FOCUS surface water scenarios
  - Annex 1 : Proposals from MSs retained for possible revision of the current FOCUS surface water scenario which are considered outside the scope of part of the FOCUS “repair action”.
  - Annex 2: Other proposals raised by MSs to the FOCUS surface water “repair action”.

- Proposal for Terms of References for preparing guidance of EFSA on completing risk assessments for active substances of plant protection products that have isomers and for transformation products of any active substances where these transformation products may have isomers.

- Proposal for Terms of References for updating the EFSA Guidance on pesticides risk assessment for Birds and Mammals, for discussion at PSN meeting 10th February 2015.

Annex

Proposal for Terms of References for "repair action" of the FOCUS surface water scenarios

BACKGROUND

The need for a "repair action" of the FOCUS surface water scenarios has been identified by EFSA. Following a commenting round with Member States and a discussion at the Pesticide Steering Network (PSN) meeting in November 2014, EFSA prepared the draft ToRs and launched a second consultation. The draft was reviewed according to the provided comments and further discussed at the PSN meeting of February 2015.

The repair action will be limited to specific elements suitable for a short-term repair action. Additional proposals received from MSs have been included in Annex 1 and will be retained by EFSA for a possible future revision of the FOCUS surface water scenarios. Due to the nature and complexity of these proposals they would not fit into the proposed timeframe FOCUS "repair action".

Requests from MSs that are already being considered through FOCUS version control and by ECPA are considered outside the scope of FOCUS surface water "repair action. These requests are listed under Annex 2 for transparency.

TERMS of REFERENCE

The Terms of Reference included below have been discussed at the Pesticide Steering Network meeting held in Parma on 10th February 2015 and considers the proposals from the network members.

The following tasks are proposed to be undertaken under the FOCUS "repair action":

1. Intoduce into the all FOCUS surface water scenarios (both runoff and drainage) a 20 year assessment period instead of the current 16 months assessment period.
2. Because of the 20 year assessment period, the way application dates are defined needs to be reviewed. i.e. PAT (Pesticide Application Timing calculator) functionality used / modified or not and if used which year to run PAT with in the context of dates for 20 years, is a critical task to be investigated and approach agreed.
3. Add substance parameter input selection guidance when these parameters are correlated with the soil properties e.g. pH.
4. Foliar wash-off coefficient used in MACRO and PRZM and the equation used to describe foliar wash-off to be reviewed. The description of wash-off in FOCUS SW was questioned in EFSA opinion on scenarios for PECsoil (EFSA Journal 2012;10(2):2562).
5. Repair should ensure that processing times of revised weather scenario definitions are not excessive and results are still easily produced and reproduced as part of regulatory assessments.
6. Repair should consider how the results are to be presented and used in risk assessment.

7. Repair to consider how rotational crops are to be dealt with in risk assessment.

Consultation of risk managers on the exposure protection goals.

After increasing the assessment period to 20 years, EFSA will together with the Working Group produce a set of alternatives to be presented to Risk Managers (RMs) and the decision from the RMs will be implemented.

Stakeholder public consultation.

A stakeholder web-consultation will be organised during the FOCUS surface water "repair action" to ensure full involvement of MSs and other stakeholders.

References.

EFSA EFSA PPR Panel, 2012a. Scientific Opinion on the science behind the guidance for scenario selection and scenario parameterisation for predicting environmental concentrations of plant protection products in soil., EFSA Journal 2012;10(2):2562, 76pp.

FOCUS, 2001. FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2, 245 pp.

Klein M, Long term surface water simulations using the FOCUS scenarios. Poster presentation at the York Conference 2013

Annex 1

Proposals from MSs retained for possible revision of the current FOCUS surface water scenario which are considered outside the scope of part of the FOCUS "repair action".

The following proposals received from Austria, Sweden and UK to the EFSA discussion note dated 7th November 2015 have been retained for a possible future revision of the FOCUS surface water scenarios. Due to the nature and complexity of these proposals they would not fit into the proposed timeframe FOCUS "repair action".

1. Concerns regarding the FOCUS exposure profiles are further substantiated by the chapter 3.3.3 on the spatial scale which states that surface waters further downstream that address environmental risks of PPPs at a larger scale (e.g. catchment) are mainly a research activity. That means that currently such water bodies are not covered by the risk assessment. Especially regarding spacing of peaks (if there are any at all, and not constant flow-through exposure) the exposure pattern might be completely different. No attempt was made in the guidance document to address this issue e.g. by adding additional safety factors.
2. Up to now the aquatic risk assessment was simply based on the global PEC (or TWA) of the individual FOCUS scenarios. In case of the runoff scenarios the global PEC is of course subject to rather high uncertainty, in particular with respect to the selection of the application window (also see above). It seems evident, that this uncertainty applies to subsequent peaks and the time between peaks of the exposure pattern as well, strongly increasing the uncertainty of overall exposure pattern (which then may be directly used for the effect assessment). Refined exposure regime studies according to predicted exposure profiles based on FOCUS directly connect exposure and effect assessment and thereby introduce the uncertainties of the exposure assessment into the overall risk assessment. As explained above distance of peaks and number of peaks are two more parameters with high uncertainties when based on FOCUS added to the risk assessment. Thus, the linkage of the effect and exposure assessment as proposed in the new aquatic GD is not supported as long as at least the degree of uncertainties in the exposure assessment is not specified. A more conservative approach with less parameter is preferred and a critical evaluation and revision of the exposure of assessment as recommended by EFSA is appreciated.
3. Review of the initial scenario selection in light of more recent advances in GIS and EU wide soil mapping information (following on from similar recommendations from the PPR Panel opinion on the selection of FOCUS groundwater scenarios).
4. Consideration of the relevance of the current standard FOCUS water bodies.
5. Consideration of the continuing relevance of the underlying spray drift data used in the current framework in light of additional data sets.
6. Some consideration of the acceptability of the assumptions regarding the treatment area in the upstream catchment should be undertaken. In areas of intensive crop production it is possible that the assumption of only up to 20% treated areas may not be a realistic worst case in line with the previously identified protection goals. The

extent of residues from up-stream catchment can have a very significant influence on the final PEC values produced at Step 3 and this is markedly influenced by the assumption of extent of treated area up-stream.

7. Easier implementation of Step 4 refinements – particularly to be linked to the MS specific requirements at product authorization level. A very useful and achievable functionality of the future model in our opinion ought to be the ability to input an ecotoxicologically derived RAC value and the Step 4 module would automatically simulate and identify the minimum buffer zone requirements (spray drift and/or runoff mitigation) needed to achieve an acceptable risk assessment.

Annex 2

Other proposals raised by MSs to the FOCUS surface water "repair action".

The following requests from MSs to the EFSA discussion note dated 7th November have not been included in the ToRs for the "repair action" as they are already being considered through FOCUS version control and by ECPA. Therefore they are considered outside the scope of FOCUS surface water "repair action".

1. Repair to the model should ideally simplify the simulation of metabolites formed in water (not currently possible in the available version of TOXSWA). This is already addressed in the next release of TOXWA that is in final stage of testing in FOCUS version control, should be released in early 2015.
2. Comment consideration of which version of MACRO most accurately reflects real world concentrations. The next release of MACRO that is in final stage of testing in FOCUS version control, that should be released in early 2015 will be the definitive FOCUS MACRO version.
3. Consideration should be given to linking the Step 4 tool directly to the VFS model if this is considered to provide a more scientifically robust assessment of the efficacy of vegetated filter strips. Current SWAN version and the next release in preparation (made available by ECPA) will do this, though EFSA is not aware of any independent assessment whether the VFS model is considered to provide a sufficiently scientifically robust assessment of the efficacy of vegetated filter strips.
4. If multi-year simulations are incorporated into the repair, it would be useful to consider the availability of tools for analysing such complex exposure profiles. Such tools may be necessary where key metrics such as peak height, duration, return intervals, duration over RAC etc are needed as part of more complex higher tier aquatic risk assessments. The currently available tool EPAT (made available by ECPA) does this.

Proposal for Terms of References for preparing guidance of EFSA on completing risk assessments for active substances of plant protection products that have isomers and for transformation products of any active substances where these transformation products may have isomers.

BACKGROUND

The current data requirements for plant protection products, establish that the active substance tested should match the technical specification (including its isomeric composition) and that formation and effects of metabolites, degradation and reaction products should be investigated. This does not exclude the case when metabolites / transformation products are isomers of the active substance / are constituted by active substance components of a different isomer ratio to that defined by the technical specification. It is also specifically indicated that it is necessary to 'establish the isomeric composition and possible metabolic conversion of the isomers when relevant;'. The information provided must be sufficient to permit an evaluation to be made on the nature and extent of the risks for man, an assessment of the fate and behaviour of the active substance in the environment and the identification of non-target species likely to be at risk from exposure to the active substance, its metabolites, degradation and reaction products, where they are of toxicological or environmental significance.

It has been estimated that around 25% of agrochemicals possess at least one asymmetric centre or other stereogenic element in their molecular structure. EFSA in its conclusions on pesticide active substances and reasoned opinions on setting or modifying maximum residue levels (MRLs), currently identifies the concern that assessments are not finalised, where further information is considered necessary on the behaviour of stereoisomers in plants, animals and the environment and or effects on non target organisms. This is concluded when this information is essential to better characterise the risk to humans and other non target organisms, because there are insufficient margins of safety in the available risk characterisation/s. When making EU approval decisions on active substances, where the EFSA risk assessments identify this concern, there are several examples where risk managers have decided to keep the substance on the market, but indicated applicants must generate studies on this, that must be submitted by two years after the adoption of a specific guidance document on evaluation of the impact of isomers on the pertinent risk assessments. Therefore the information necessary to address this concern that is highlighted by EFSA, will only ever be addressed after a guidance document is made available.

TERMS of REFERENCE

The Terms of Reference included below have been discussed at the Pesticide Steering Network meeting held in Parma on 10th February 2015 and updated considering the proposals from the network members.

Based on this background information and the discussions at the Pesticide Steering Network, the Pesticides Units proposes to develop an EFSA guidance that addresses

appropriate practice for completing risk assessments for active substances of plant protection products that have isomers and for transformation products of any active substances where these transformation products may have isomers. The main focus of the guidance will be stereoisomers because of the additional analytical challenges characterising this class of isomers. However the guidance will also cover structural isomers.

The users of the guidance will be applicants, consultants preparing applications, competent authorities of the Member States and EFSA staff.

The guidance document developed should be consistent with the regulatory framework and data requirements for pesticides under Regulation (EC) No 1107/2009. This framework has the aim of covering the risk to humans (in particular workers, bystanders, residents, consumers of treated produce, consumers of animal products derived from animals that have consumed treated produce, consumers of contaminated groundwater (primarily in the context of non relevant groundwater metabolites)) and other non target species (terrestrial and aquatic wildlife, wild birds and domestic animals used for food production). The risk assessment paradigms currently used (regarding indicator species selected, matrices in which exposure assessments are made and their temporal and spatial definitions) as set out in the legislation and existing noted guidance should not be changed by this guidance. The guidance needs to work with the risk characterisation approaches currently used. As far as is possible, the guidance will be developed with the aim of being compatible with risk assessment guidance that is being updated / is under development or may be developed in the future. This guidance will make use of the considerations already made regarding stereoisomers in the EFSA (2012) panel on plant protection products and their residues (PPR) scientific opinion on evaluation of the toxicological relevance of pesticide metabolites for dietary risk assessment. The aim of the guidance is to provide practical advice that uses available proven analytical and other technologies. The intended consequence of following the guidance, is that the uncertainty of a risk characterisation for a substance that contains isomers not resolved by non chiral analytical techniques or one that transforms to substance/s with such isomers, should not be greater than for substances that do not have these properties. The guidance will aim to deliver the same level of confidence in the risk characterisation when there are isomer issues, as for a risk characterisation where there are no isomer issues.

Topics for which guidance needs to be developed are:

- Terminology used for describing different types of isomers with examples,
- Description of the capacities of different analytical techniques to discriminate and quantify different types of isomers,
- Guidance on uncertainty factors in the different risk assessments to be applied, without information on exposure and or effects from individual stereoisomers, being available, i.e. the factors needed when ‘sum of isomers of unknown composition approaches’ are followed.
- Guidance on the proportion of samples in the different radiolabelled metabolism study designs requiring stereoisomer separation, to provide sufficient information on exposure patterns of individual isomers (plants, animals, soil, sediment/water) when ‘sum of isomers of unknown composition approaches’ are insufficient for a robust risk assessment.
- Guidance on what change in stereoisomer ratio is considered too small to conclude that existing uncertainty factors used for risk assessment have not been eroded,

- Guidance on the need for non-radiolabelled residues (in plants, domestic animals, soil) studies to include some quantitative information on stereoisomer levels, guidance on interpretation of such studies and using this information in the exposure assessment where this information is available.
- Guidance on interpreting mammalian absorption, distribution, metabolism and excretion studies where information on stereoisomer ratios has been provided by the available analyses, guidance on interpretation of the studies where this information is available
- Guidance on approaches, study designs and test organism selection, when risk characterisations indicate that toxicological or ecotoxicological reference values need to be determined for individual isomers or isomer compositions that differ from those in the technical substance originally tested.

It is envisaged a public consultation will be organised on a completed draft document. The target time to initiate the consultation is 2/3 of the way through the project. A stakeholder report will be prepared and input from the consultation considered, when finalising the guidance of EFSA.

References

EFSA (European Food Safety Authority), (2012). Scientific Opinion on evaluation of the toxicological relevance of pesticide metabolites for dietary risk assessment. The EFSA Journal (2012) 10(07): 2799. Available online: www.efsa.europa.eu/efsajournal

EMEA (European Medicines Agency), (1993) Clinical investigation of chiral active substances, reference number 3CC29A http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002816.pdf

HSE (Health and Safety Executive), Safety evaluation of isomeric mixtures Part 1 General considerations http://www.pesticides.gov.uk/Resources/CRD/Migrated-Resources/Documents/A/aahl0201_isomers1.pdf

HSE (Health and Safety Executive), Safety evaluation of isomeric mixtures Part 2 testing chiral organophosphorous compound for delayed polyneuropothy http://www.pesticides.gov.uk/Resources/CRD/Migrated-Resources/Documents/A/aahl0201_chiral20Opss2.pdf

Liu, W., Gan, J., Schlenk, D. & Jury, W. A. (2005) Enantioselectivity in environmental safety of current chiral insecticides. Proceedings of the national academy of science of the United States of America 102 (3) p701-706.

Wong, C.S. (2006) Environmental fate processes and biochemical transformations of chiral emerging organic pollutants. Analytical and bioanalytical chemistry 386 p544-558.

Proposal for Terms of References for updating the EFSA Guidance on pesticides risk assessment for Birds and Mammals, for discussion at PSN meeting 10th February 2015.

BACKGROUND

In order to gain EU Level approval of an active substance under Regulation (EC) 1107/2009, it is necessary to demonstrate that there are no unacceptable risks to bird and wild mammals. Since the early 2000's to 2009 the main guidance document used for the risk assessment of plant protection products for birds and mammals was the 'SANCO/4145 Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC, European Commission (2002). However, in 2009 the European Food Safety Authority (EFSA) issued a new guidance document ('Risk Assessment for Birds and Mammals', EFSA, 2009).

Since the development of the EFSA (2009) guidance document, the PPR Panel developed a framework for deriving specific protection goals (EFSA PPR Panel, 2010a). The approach outlined in that opinion will be the starting point for the development of the updated guidance document for birds and mammals.

Since the publication of EFSA (2009), Regulation (EC) 1107/2009, Regulation (EU) 283/2013 and Regulation (EU) 283/2014 have been implemented. There have also been new scientific developments and data (EFSA PPR Panel Opinions and EFSA Guidance Documents.

Therefore, where necessary, it is considered appropriate to update the risk assessment methodology of EFSA (2009) taking account of the new legislative framework and the recent scientific research and developments.

TERMS of REFERENCE

The Terms of Reference included below have been discussed at the Pesticide Steering Network meeting held in Parma on 10th February 2015 and updated considering the proposals from the network members.

In addition to the elements mentioned in the background information, with this revision, aspects of the guidance document, which are considered to need further clarification, will be elaborated. A consideration will be given of if, and how, further harmonisation of the risk assessment can be achieved, e.g. within regulatory zones.

Topics for which guidance needs to be developed are:

- Update the EFSA (2009) guidance document in view of the PPR Panel Opinion on protection goals.
- Update the EFSA (2009) guidance document in view of Regulation (EC) 1107/2009, Regulation (EU) 283/2013 and Regulation (EU) 284/2014.
- Update the risk assessment methodology in light of scientific research and developments.
- Update the EFSA (2009) guidance document in view of the feedback from Member States and other stakeholders.

- Provide clarifications on the current methodology where needed.
- Consider the possibility of further harmonisation of higher tier risk assessment within EU regulatory zones.
- Consider the possibility of providing a calculator tool to accompany the updated guidance document.

It is envisaged a public consultation will be organised on a completed draft document. The target time to initiate the consultation is 2/3 of the way through the project. A stakeholder report will be prepared and input from the consultation considered, when finalising the guidance of EFSA.

REFERENCES

European Commission, 2002. Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC. SANCO/4145/2000.

EFSA (European Food Safety Authority), 2009. Guidance Document on Risk Assessment for Birds and Mammals on request of EFSA. EFSA Journal 2009; 7(12):1438[358 pp.]. doi:10.2903/j.efsa.2009.1438.

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

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2014. Scientific Opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products. EFSA Journal 2014;12(3):3589 [92 pp.]. doi:10.2903/j.efsa.2014.3589.

EFSA (European Food Safety Authority), 2014. Draft EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil.

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.

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.