PESTICIDE RESIDUES UNIT

DEDICATED PESTICIDE STEERING NETWORK ON MRL PROCEDURES AND RESIDUE ASSESSMENT IN GENERAL

MINUTES OF THE 2nd dedicated MRL PSN MEETING

Held on 04-05 November 2019, Parma

(Agreed on 27 November 2019)

Participants

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

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  Elena BARZDENIENE (Lithuania)
  Helena BASA (Slovenia)
  Marek CERNOCH (Czech Republic)
  Maria GASPARI (Greece)
  Ingo GROSSSTEINER (Austria)
  Bodil Hamborg JENSEN (Denmark)
  Mitsuko KOMADA (Norway)
  Kristof KOVACS (Hungary)
  Eva KRASCSENITSOVA (Slovakia)
  Eva LIND (Estonia)
  Tiia MAKINEN (Finland)
  Laura MISINA (Latvia)
  Aleksandra NEYKOVA (Bulgaria, via teleconference)
  Finbarr O'REGAN (Ireland)
  Jose Luis Alonso PRADOS (Spain)
  Marina RUSCH (Germany)
  Xavier SARDA (France)
  Marloes SCHEPENS (the Netherlands)
  Pawel STRUCINSKI (Poland)

Chantal VERVAET (Belgium)

Anneli WIDENFALK (Sweden)

Alicia YAGUE MARTIN (Spain)

- European Commission representatives:

  Marc LEGUEN DE LA CROIX (DG SANTE)

- EFSA:

  Pesticide Residues Unit (Bénédicte VAGENENDE, Head of Unit a.i., Chair)

  Pesticide Residues Unit (Luna GRECO)

  Pesticide Residues Unit (Luis CARRASCO CABRERA)

  Pesticide Residues Unit (Hermine REICH)

  Pesticide Residues Unit (Alba BRANCATO)

  Pesticide Residues Unit (Samira JARRAH)

  Pesticide Residues Unit (Luc MOHIMONT)

  Pesticide Residues Unit (Alessia VERANI)

  Pesticide Residues Unit (Angela SACCHI)

  Evidence Management DATA Unit (Jane RICHARDSON)

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted with the following additions:

- EE: clarification is requested regarding applying corrections for measurement uncertainty in the case of exceedance of MRLs and ADI.
- AT: clarification is requested regarding the mammalian toxicological assessment in case the cut-off criteria are met.
- DE: following discussion in PAI group, several MS request EFSA to consider creating a WG on the grouping of metabolites.
- NL: an additional point is proposed regarding the assessment of common metabolites.

3. Topics for discussion

3.1. Art. 12 new process: clarifications, roles of different actors, agreements, timelines, handling of uses in third countries and import tolerances

EFSA gave an introduction on the draft work instructions shared with Member States (MSs), EURLs and SANTE before the meeting and on the scope of this discussion. The new procedure was discussed and agreed with Commission and Member States at the Pesticide Steering Network meeting in June 2014 (see the minutes in the link https://www.efsa.europa.eu/sites/default/files/event/140619-m.pdf), was tested with a first pilot (glyphosate) in 2016 and started to be routinely used in 2017.

During the PSN, EFSA presented a modified version of the process, including a new step for the validation of the GAP overview file by EFSA and clarifying the involvement of the EURLs. The procedure as agreed in 2014 and the modified version to be agreed upon with MSs are reported in Appendix A.1 and A.2, respectively.

Main scope of the discussion:

- to check the **feasibility of the timelines**.
- **to check if import tolerances are sufficiently covered by the procedure**.
- **Discuss and agree the approach for the GAP overview file.**
- **Discuss and agree the proposed modification of the procedure including validation by EFSA of the GAP overview file.**
- **Ensure that the procedure and roles are clear to actors involved and that the instructions** (expected to be publicly available to third parties next year) cover and address the main problems MSs encountered so far with the procedure.

As the basis for discussion EFSA presented the work instructions as prepared and shared before the meeting.

The following points were highlighted by EFSA:

- Importance to have clear GAPs submitted by MSs at the very beginning of the procedure (step 2);

- Importance that MSs submit only the 2-3 most critical GAPs authorised for each crop and geographical zone (pre-screening of GAPs) (step 2);
- Importance that MSs report in the GAP form, a reachable link to the zonal assessment or re-registration report, if available on CIRCABC (step 2);
- Importance that RMS checks the data available to support the most critical GAPs, at the time of the identification of the most critical GAP (step 3a);
- Importance that RMS submits a complete GAP overview file (columns W-Z filled in) (step 3a);
- Importance that the RMS includes in the evaluation report submitted together with the PROfile the summaries of the trials and the studies considered to support the most critical GAPs, although already assessed in the evaluation reports submitted by MSs or in re-registration reports or zonal assessment (step 5);
- Importance that the RMS updates the GAP overview file after the data collection (a tool allowing the RMS to import automatically the GAPs from the GAP overview file into the PROFile is currently under development);
- Importance to have the most critical GAPs and the supporting data included in the PROFile, in order to calculate MRLs and risk assessment values for plant and animal commodities, identify the GAP driving the MRLs and fall-back GAPs, if needed.

Moreover, EFSA clarified the role of EURLs which were proposed to be involved during the collection of data (Step 4) and during the Consultation of MSs on the draft reasoned opinion.

The following comments/issues were raised by MSs:

- Importance of having authorization holders better informed and more involved in the procedure;
- Need to involve not only the RMS but also other MSs for the submission of the import tolerances;
- Difficulty in coordinating among MSs for both GAPs and data submission;
- Need to align the validation criteria included in the GAP form and in the GAP overview file, to the BBCH growth stages as reported in the guidance document on extrapolation;
- Need to modify the unit for the application rate available in the scroll-down menu of the GAP form in order to cover microorganisms and to reduce the options given (eg. deleting g/hL);
- Need to be informed by EFSA when there are delays along the procedure;
- Need to be informed by EFSA at the time of the Consultation of MSs on the draft reasoned opinion that a new residue definition has been proposed in the assessment;
- Need to avoid that unnecessary work is requested to be done by RMS and MSs.

The following points were agreed by MSs:

- To set a timeline of 6 weeks for the preparation and the submission of the GAP overview file by the RMS (step 3(a));
- To include in the process a step (3(b)) lasting 2 weeks, to allow EFSA validating the GAP overview file.

After the meeting the work instructions were revised by EFSA to address comments and concerns expressed by MSs as reported above. The revised work instructions were further circulated for commenting and agreement.

3.2. Art. 12: GAP overview file (training)

As part of the action points requested by MSs (PSN, April 2019), EFSA organised a practical training on the use of the GAP overview file. The recorded version is made available to MSs under EFSA DMS (link) .

3.3. Cumulative risk assessment

EFSA updated MSs on the status of the cumulative risk assessment project, the outputs published so far and the related next steps. EFSA first illustrated the legal context and the overall timeline of the process, from the development of a methodology for pesticides to the design of the first pilot and the parallel cross-cutting activities. EFSA presented the design of the pilot project (focusing on two target organs (nervous system and thyroid), considering certain specific effects), the problem formulation and the three work packages of the risk assessment (hazard identification and characterization; cumulative exposure assessment; risk characterisation and uncertainty analysis). A final overview of the outputs published in 2019 was provided: two scientific reports on the Cumulative Assessment Groups, the related public consultations reports, four reports on the exposure (MCRA and SAS). The public consultation is currently on going on the two final outputs on the risk characterisation, which will be finalised in March 2020. A stakeholder event was held in October 2019.

IE commented that if the pool of monitoring data considered for the CRA covers the years from 2014 to 2016, it could be that some of the residue data considered are from active substances which in the meantime were banned from the EU market. IE asked whether it is foreseen to update the assessments looking at most recent years (2017,'18,'19) in the future and if yes, when.

EFSA confirmed this is foreseen, but at the current moment specific timelines cannot be provided.

3.4. MATRIX project

The project aims to standardize and structure the dossiers, to have a single access point for the dossiers of all regulated products, to check and communicate the status of the application and to have a cohesive channel for communication.

EFSA aims to have a more transparent and traceable approach of the scientific risk-assessment that would be more data-driven. This is a direct follow up in view of the main changes to be implemented by the Transparency Regulation[1] in terms of transparency, confidentiality and scientific excellence. Main changes: proactive publication of data and information; centralised decision making on confidentiality by EFSA in most of the processes; strengthened scientific support to applicants, and particularly SMEs; improved design and coherence of studies underlying EFSA scientific outputs.

A survey was run with the members of the EFSA Pesticide Steering Network in June 2019 to see what inhouse systems are used for the submission and processing of dossiers. Responses were received from 17 organisations from 11 countries. Most of the respondents use a file system and CADDY viewer to review pesticides dossiers, while for other organisations more advanced document management systems, digital archives and in-house systems are being used to store dossiers and create assessment reports.

[1] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC. PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

EFSA is currently running a pilot to investigate the suitability of IUCLID for pesticide dossiers, chosen as the most complex example of structured dossier among the different procedural workflows for regulated products The aim is to identify required adaptions for inclusion in future IUCLID releases and to provide feedback to support the definition of a target solution for possible inclusion in the Transparency Regulation deliverables (March 2021).

A Pilot Technical committee of six MSs, two industry associations, ECHA and EFSA has been established, plus an external contractor for the creation of a proof of concept dossier to be used in the pilot. The pilot will be run in two execution phases respectively in Nov 2019- Feb 2020 and Nov 2019-April 2020. In April 2020 a meeting venue with the technical committee is foreseen. EFSA clarified that MS for the technical committee were selected based on the expression of interest and in order to cover different levels of experience with systems for the dossiers submission.

EFSA noted that under the pesticides framework other parallel inhouse projects for the achievement of a more structured submission of information are on-going, such as the one for implementation of BfR RUEDIS Database (collection of data from field trials, storage stability and processing studies) or the OECD Metapath (to populate the database on metabolism studies).

AT asked if it is considered to also revise the evaluation templates. EFSA confirmed that for the time being OECD templates and summary reports from biocides previous experience have been considered. IE asked whether it is foreseen that IUCLID will allow direct transfer of information from the data base to structured evaluation/assessment reports. EFSA confirmed that first a solid completeness check step is needed before starting to work on the structure of summary reports and then, of the assessment reports. During the current pilot EFSA is already selecting some validation rules that will need to be further explored to build a robust validation system.

ES and FR asked whether the pilot is covering both active substances and plant protection products (PPP) and if it was considered that at national level different regulations apply for management of confidentiality. EFSA clarified that the current pilot will focus on a.s, however a IUCLID submission template has been also created for PPP. Obviously depending on the interest of MS this can be further explored.

It was also confirmed by EFSA that EC is closely involved in the project, eg in view of the possible use of FSCAP platform (used in novel food and food additives frameworks) for the management of the different information streams for the administrative part of the applications.

3.5. GAP table in excel

EFSA presented the ongoing pilot project on using a GAP table in Excel format to describe the intended uses/authorised uses for which MRL applications are submitted in the framework of Art. 6 to 10 of Regulation (EC) No 396. The pilot has been running since December 2018, where EFSA translated the GAPs in the excel form submitted within the MRLs applications and asked for validation to MS as a follow up step. The exercise was useful to gain experience and to identify options for improvements of the Excel tool.

The aim of the new format for the GAP table is to avoid ambiguities on the GAPs that are the basis for the MRL. Experience has shown that during the detailed assessment of MRL applications, EFSA identifies the need for further clarifications of the GAPs. The requests for clarifications often lead to delays in the assessment which could be avoided.

EFSA highlighted that further improvements of the Excel file are under preparation which will facilitate the completion of the GAP table. In addition, standard terminology for the certain parameters (drop down lists) and standard codes will be integrated, where possible.

EFSA believes that the 'translation' of GAPs into excel format opens new possibilities for identifying which data need to be submitted in support of an MRL application to support a GAP.

DE and FR asked whether it is foreseen to use the excel format also under other frameworks (peer review but also PPPs authorisation), it was highlighted that moving towards one single format for all processes is considered essential in order to avoid copy and paste and increases risk of errors.

EFSA reiterated that, as previously announced to both PAFFs (Legislation and Residues) the final aim is to build a comprehensive excel GAP table to be used under MRLs , peer review and plant protection products assessments, with specific functionalities to be developed that will easily allow to switch from one process 'view' to another. EFSA is also exploring further possibilities to align with other domains, such as national authorisations (SANTE PPPAMS database). The need for having a GAP table in structured format is also crucial in view of the structured data required under the Transparency Regulation (cfr item 3.4). MS consultations are planned through the respective PAFFs in 2020.

However, since the MRL assessment part is more advanced, EFSA would like to investigate with MS the possibility to start using and testing it under current art.10 applications and build experience to be considered in the development of the comprehensive GAP table.

A question on the possibility to directly change the GAP table format that is currently in the application form instead of including the new GAP in the ER was raised by DE, and potentially confirmed by EC, upon proper formal agreement at the PAFF (taking note of a new revision of the application form). A possibility could be to remove the Annex from the application form and include alongside the document the GAP excel file. NL flagged that the GAP is under the responsibility of the applicant, so better to consider the option of having the excel file directly with the application form.

FR highlighted the importance not to deviate too much from the OECD template format which is considered the basis to harmonise the approach also outside Europe. EFSA confirmed that the proposed GAP table is fully compatible with the OECD template and the same elements have been included into the excel file. It was agreed that during the exercise it should be considered proper time and space for discussion also at OECD level.

AT proposed to continue with the pilot until end of 2019 and then consider moving to the next steps of the exercise in 2020.

Action point: MS are kindly invited to express their interest in using the excel GAP table for incoming art.10 applications. First experiences and feedbacks will be considered for further improvement of the file.

3.6. Art. 10: Crop Categorisation Library

EFSA presented a first draft of a tool developed inhouse with the aim to help identifying the data required to support MRL applications, starting from the related intended uses (GAP). The library is basically an overview of data requirements related to the individual crop as defined in the technical guidance documents for pesticides residues in food and feed under the two regulatory frameworks: Regulation (EC) No 544/2011 (so called "old data requirements" or "Lundehn documents") and Regulation (EC) No 283/2013 ("new data requirements" or "OECD guidance").

The library tool is an excel overview table, where rows correspond to individual plant products/crops as listed in Annex I to Reg (EC) No 396/2005 (at individual crop level, not at crop group) and certain feed items, while the columns report the grouping of each individual plant product according to the old/new data requirements (i.e. based on primary crop metabolism, analytical method validation, freezer storage stability, crop rotation relevance, relevance in livestock or aquaculture, distribution in major crops per region, production method, etc.)

Basically, the library can be used as reference material, to gather certain data requirements in a single place, as a checklist in the assessment process of the application, to support guidance interpretation and knowledge transfer. Additionally, the library is giving the opportunity to compare and discuss possible harmonisation of differences within the 2-classification (old/new) for certain crop or to identify guidance documents candidate for replacement.

A short demonstration of the Crop Categorisation Library, its capabilities and limitations was given. Information which is not sufficiently detailed or is missing in the table was proposed to be elaborated and agreed upon.

For ES crop categorisation is a useful exercise, however 'residues' is not the only area for which it would be useful, as crop categorisation is also linked for example to environmental risk assessment. If the aim of the exercise is to build validation rules for possible future implementation in IUCLID system, then we need to expand the discussion and also consider that crop categorisation might differ at national level and would need to be harmonised among different national data bases and approaches.

EC reminded that when certain guidance documents are considered 'obsolete' for assessment purposes cannot be simply deleted. it would be useful to create a list of those and then check whether they are covered by new guidance. Then, the indications on how to implement new data requirements should be revised accordingly.

Action point: MS will be kindly invited to provide feedback on the library in order to consider the need and plan further activities. A survey is under elaboration and will circulate at the earliest convenience.

3.7. Art. 10: list of endpoints as part of evaluation report, exchange on structure evaluation report

EFSA presented a proposal for inclusion of the LoEP as part of the ER. The benefits of this proposal would be:

- To have a clear overview of the MRL assessment undertaken by the EMS, which data and conclusions coming from previous assessments are still considered valid and applicable and which new data have been submitted and evaluated in support of the new MRL application.
- Streamline the drafting: no need to include long narrative assessments where no new data has been made available. Reference to previous assessments would be sufficient. Drafting would be mainly focused on the assessment of the new information with clear reference to the LoEP.
- The new provisions in the Transparency Regulation: The inclusion of the LoEP will support a more transparent, structured and clear presentation of the assessment, that will help the implementation of the transparency measures.

Practical instructions were given to EMS on how they could access to the word version of the most recent LoEP published within an EFSA output and on how to update it for their specific MRL assessment.

EFSA also reminded MS the importance of submitting the last updated version of the supporting dossier when submitting the final Evaluation Report concerning a certain MRL application. In case an updated version of the supporting dossier is submitted following a clock stop letter from EFSA, EMS should ensure the updated dossier is also submitted to EFSA. Furthermore, MS are invited to submit any further document/tool/structured format they use inhouse for the assessment of art.10 MRLs applications (calculators, excel files, compilation of residue trials, etc.).

DE flagged that the LoEP should be a stand-alone document and not included in the ER, as it is the case for the peer review process. EFSA confirmed that this can be considered.

FR supported the idea and the usefulness of having a LoEP alongside the ER, however expressed doubts concerning its practical inclusion in the ER, as the LoEP is an official document agreed at the PAFF when the active substance is approved by risk managers. EFSA clarified that the Review Report published by EC is limited to the first pages of the LoEP and refers to the full document as published EFSA.

Furthermore, EFSA reiterated that no changes in current risk assessment and its presentation in the EFSA Reasoned Opinion are foreseen. Even if the LoEP was included in the initial ER, still the appendix as drafted by the EMS would be assessed and finalised by EFSA, and then published as usual alongside the Reasoned Opinion, as it is currently done for all EFSA pesticides outputs.

Action point: MS willing to volunteer for testing the use of the LoEP as part of the ER, are kindly invited to express their interest.

3.8. Residue definition for risk assessment applicable for Art. 10 MRL applications

EFSA provided an overview of the regulatory life cycle of an active substance and the different cases where residue definitions for risk assessment are modified. EFSA highlighted that it is essential to provide clarity not only which residue definition becomes applicable, but also when it becomes applicable and which data need to be provided by whom in case the residue definitions are not fully supported by data (provisional residue definitions). Considering that the current practice of revising residue definitions for risk assessment leaves a lot of open issues, EFSA proposed further discussions at PAFF level to agree in a transparent way on the approach to be implemented.

EC clarified that the PAFF Residues is responsible for the note taking of the RD-Mo, whereas the only formal note taking of RD-RA is at the PAFF Legislation as part of the (non)approval decision. If new uses are intended and not covered by the residue definition derived for representative uses this needs to be discussed at both PAFFs. It is therefore clear from the EFSA presentation that there is the need to find other time points among the procedure when to agree and vote on the RD-RA.

NL asked if this is contradictory with the instructions given in the EC guidance document on MRL setting (quote *"As a general remark and without prejudice to the provisions of Article 14(8) of Regulation (EC) No 178/2002 (General Food Law)5 , new residue definitions and toxicological reference values that are recommended by EFSA in Reasoned Opinions or under the framework of the peer-review, should not be considered in routine risk assessment or used for enforcement purposes until the relevant PAFF has taken formal note of them"*. EC clarified that the guidance document on MRL setting only covers the note taking of toxicological reference values and residue definitions for enforcement purposes and not specifically residue definitions for risk assessment.

MS agreed that more clarity and transparency on which residue definition for risk assessment applies is needed. MS also generally agreed that a procedure for formal note taking in PAFF Committee would be desirable and therefore further discussion should be tabled at the PAFF. AT pointed out that a database on agreed residue definitions for risk assessment would be very useful and appreciated.

Action point: MS to provide comments on the presentation of EFSA. MS are also invited to bring new examples and cases with regards to the subject that can help the further discussion. A summary of the feedbacks collected can be presented at a future PAFF in order to consider the need for further discussion and follow-up actions.

3.9. Pre-submission support in peer review

EFSA currently provides advices (mainly via e-mails), supporting the RMSs during the pre-submission and/or at the early stage of the risk assessment phase in case complex scientific issues are encountered (e.g. clarification of testing strategy, overall risk assessment approach, further studies required or not, acceptability of the studies, interpretation of the test guidelines, etc…). EFSA generally provides support/advice to RMSs. If EFSA is directly contacted by the applicant, the response will be copied to the RMS or applicant will be asked to liaise with RMS before any further response of EFSA. It should be highlighted that the support that EFSA provides through the written procedure or during the APPL-RMS-EFSA pre-submission meeting (for particular questions) is **without prejudice to the upcoming peer review**.

EFSA wanted to share the experiences collected so far in the framework of the pre-submission advice provided in the residue area and presented some practical examples with the purpose to clarify what are the mutual expectations from both the RMSs and EFSA.

EFSA reiterated that it is crucial for an efficient collaboration that a preliminary assessment is carried out by the RMS regarding all the available and relevant residue data in relation to the requested support and scientific advice on a specific scientific topic during the pre-submission; so that EFSA can provide in a reliable way an opinion/advice related to the question.

AT asked which should be then intended as the border line between a preliminary assessment performed by the RMS and the pre-submission advice provided by EFSA. EFSA clarified that it is really important that the specific advice request made by the RMSs should be underpinned by a comprehensive assessment of all the available residue data; the general "context" of the active substance (e.g. toxicological profile of the substance and of the potential degradation products, representative uses, etc…) as well as a clear position/scientific expertise of the RMS on a specific issue (acceptability of a new study, position paper, etc..) should be given by the RMS to help EFSA to provide an advice.

EFSA also reminded the MSs to consult the inventory of the questions received through different channels, including the pre-submission advice framework, together with the related EFSA's responses that is available on the EFSA document management system. ("Q&A Inventory" file).

3.10. PRIMo 3.1 (training)

The new version of the model (v3.1) was published on 29 March 2019. Following up the request from MS during the PSN held in April 2019, EFSA organised a practical training on the tool and its functionalities. A recorded session of the training will be made available to MS experts on the EFSA document management system.

EFSA also provided a small update on the next version of the PRIMo (v.4). PRIMo 4 will represent a significant change as the model will be based on the EFSA comprehensive consumption data (including infants and young children) and the tool published by EFSA in early 2019 for linking consumed food with raw primary commodities. The first step will be the definition of technical specifications in terms of input data, algorithm and model output, including 5 case studies in SAS to compare with PRIMo 3. *Ad-hoc* consultation of a small group of MS on technical specifications will be launched in early 2020. A stakeholder consultation is also foreseen on the prototype, before its finalisation.

DE asked clarification on which version of PRIMo to be used. It is noted that the following subject is under discussion at risk management level and possible decision will be further discussed in the PAFF Residues on 25-26 November 2019.

FI highlighted that enforcement Authorities faced problems with the new model and asked EFSA to kindly consider providing more guidelines on the use of the tool to the monitoring network.

Action point: MS to express their interest in joining the technical group for the development of the technical specifications for PRIMo 4.

4. Any Other Business

4.1. Qualifying results with measurement uncertainty (proposed by EE)

Estonia aske MS to share their national approaches applied for MRL enforcement triggering specific risk management actions in case samples analysed in national monitoring programmes exceed the MRL. In particular, Estonia is interested to learn whether the measurement uncertainty is taken into account when the risk assessment is performed, to decide whether a Rapid Alert Notification is required or if products need to be recalled from the market.

EC referred to the "Guidance document on analytical quality control and method validation procedures for pesticide residues and analysis in food and feed (SANTE/11813/2017)". Specifically, to point E10: where it is stated that a prerequisite for the use of the 50% default expanded MU is that the laboratory must demonstrate that its own expanded MU is less than 50%. In cases where an exceedance of an MRL is also an exceedance of the acute reference dose, an expanded MU with a lower confidence level can be applied as a precautionary measure.

However, is up to the national monitoring authority to decide which value to use for the risk assessment. Most of MS confirmed that they usually use the measured values from monitoring programs as direct input values in the PRIMo, without correcting the result by the measurement uncertainty.

4.2. Cut-off criteria which reference values to be used (proposed by AT)

EFSA clarified that the reference values to be used should be the ones peer reviewed and for which it has been taken note. Even if the substance is not approved at EU level, usually peer reviewed reference values are note taken and should be considered in follow up assessments (see case of Iprodione). AT raised a question on the specific case of quinoxyfen, a non-approved active substance for which toxicological data were not peer reviewed; should they then be evaluated under Art.12? EFSA confirmed that the toxicological data will be considered, and peer reviewed under the Art.12 framework, if needed, experts meeting will be organised accordingly.

4.3. Grouping of metabolites (proposed by DE)

EFSA reiterated that the EFSA Guidance "on the establishment of the residue definition for dietary risk assessments" is not yet officially note taken so it should not be used. However, it is noted that applicants already started using it for certain aspects of the assessment such as the QSAR and the grouping of metabolites.

An update was provided by EC on the status of the work ongoing at OECD level.

DE requested if there is the intention from EFSA to create a specific working group on grouping of metabolites. EFSA mentioned that the topic was recently discussed at the general toxicological experts meeting and more instructions will be published alongside the related technical report on

how to present the data for proper discussion at the experts' meetings. However, there is no intention to create a specific working group now, as the guidance is not note taken and in principle should not be used. EFSA will further discuss this internally with the mammalian toxicology team.

4.4. Assessment of common metabolites (proposed by NL)

NL raised the general point that it would be nice to have a more harmonised approach between MS and EFSA on how to deal with the assessment of common metabolites. It is noted that the assessment of TDMs is more advanced respect to other common metabolites groups and an assessment strategy has been recently presented to PAFF. In general, it was agreed among the participants that this is a big topic that should be discussed in the broader framework of the peer review. A general principle identified is however that, when for common metabolites to certain active substances agreed endpoints are identified, the most critical ones should be used. For certain common metabolites (such as for the sulfonylureas) EFSA established a specific data base of the related endpoints which is shared with MS to help them identifying proper endpoints for the risk assessment (see link).

4.5. Dedicated PSN on residues: usefulness and frequency of the meetings

EFSA explored with MS the usefulness of a dedicated PSN meeting on residues and MRL setting and the possible frequency of such meeting.

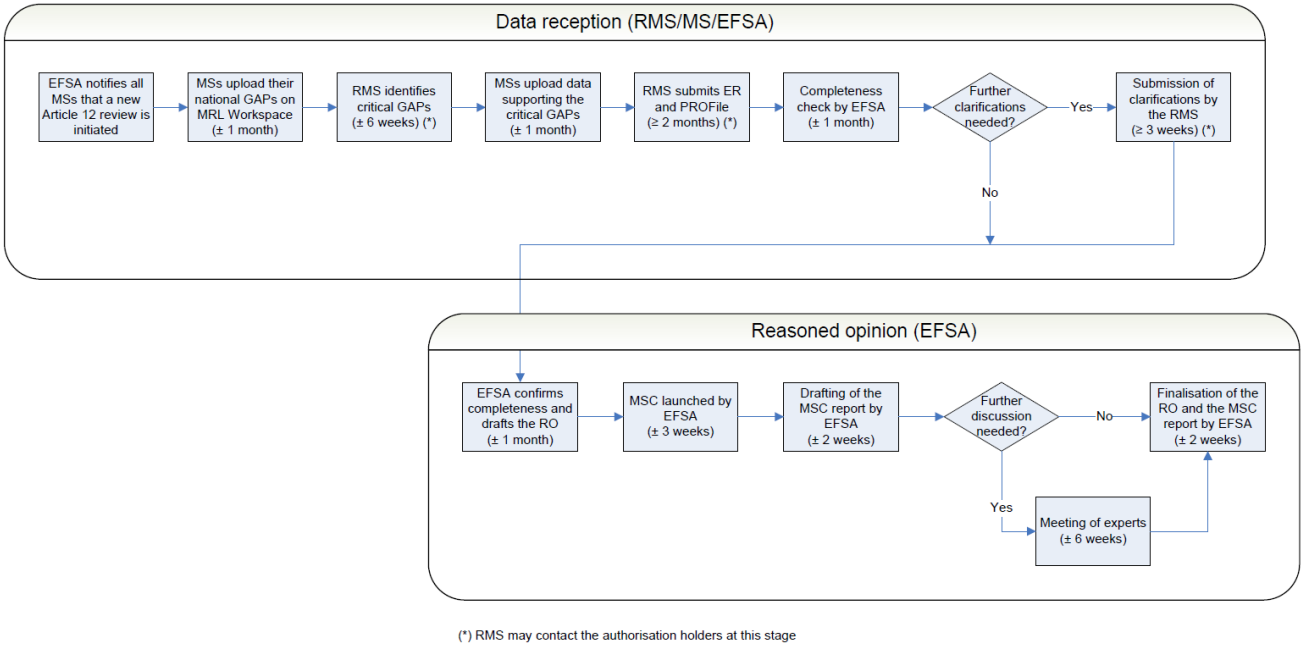
In general, FR, AT, NL, ES agreed on the usefulness of the meeting, a possible frequency could be once every year/year and a half, based on the availability of agenda points. AT suggested to have a common platform where to collect agenda points, and then to organise a meeting when a sufficient number of proposals is collected.

ES shared the usefulness of this kind of meeting especially for the discussion of horizontal matters. DE suggested to avoid that general information which is also shared through other EFSA platforms is presented under this forum, while using this specific meeting to have more focused discussion on MRL assessment is very useful (see for example the practical trainings provided).

5. Date for the next meeting

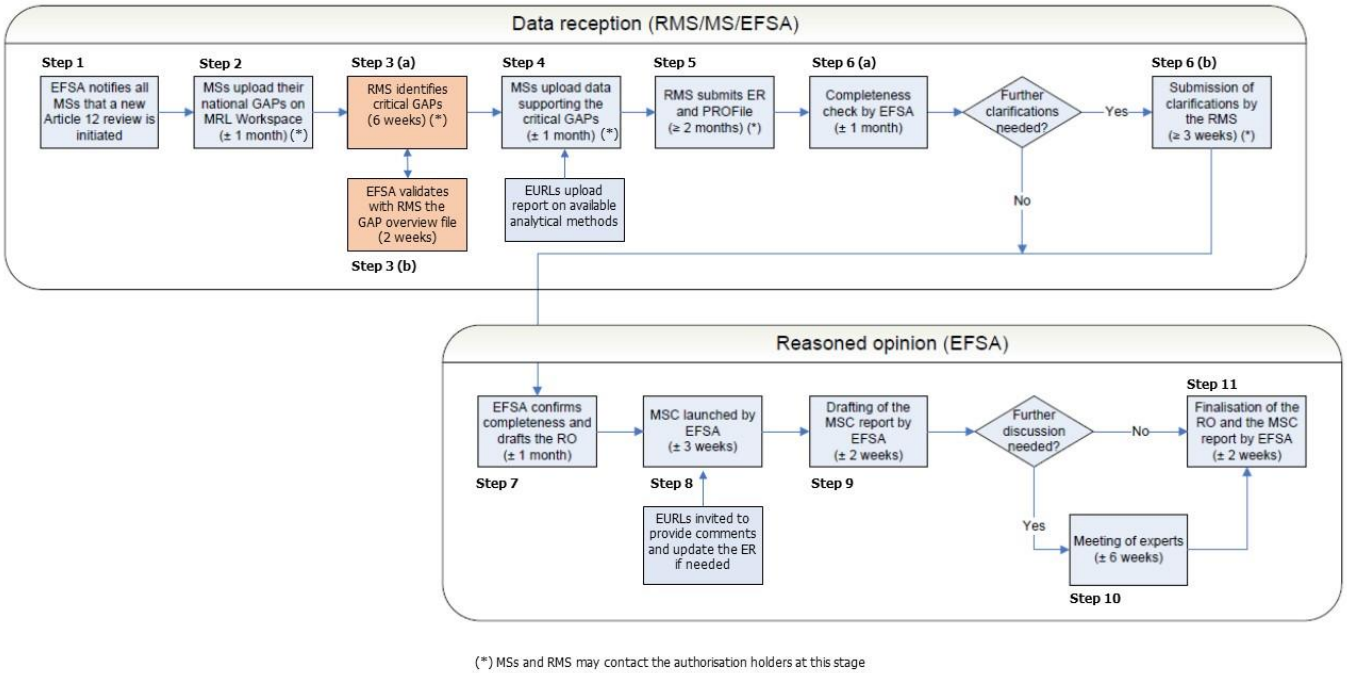
The date for the next dedicated Pesticide Steering Network on MRL procedures and residues assessment will be decided at a later stage, upon identification of agenda items in the remit of residue risk assessment and MRL setting.

Appendix A.1– Flowchart of the Article 12 procedure (as agreed in 2014)



(*) RMS may contact the authorisation holders at this stage

Appendix A.2 – Modified flowchart of the Article 12 procedure (to be agreed)



(*) MSs and RMS may contact the authorisation holders at this stage