EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

sante.ddg2.g.5(2016)7415585

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 06 OCTOBER 2016 - 07 OCTOBER 2016

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/ed11fa67-4b23-4905-a7e8-09ad6ecdaa5a*

A.01 Summary Report of previous meetings.

It was confirmed that the summary reports from the meetings held in May and July had been published.

A.02 New active substances:

1. New admissible dossiers to be noted:

i. *Paraffin oil [CAS 64742-55-8] Petroleum oils*

Paraffin oil with CAS number 64742-55-8 is an insecticide. The Rapporteur Member State (RMS) is Greece and the applicant is Brandt Europe. Admissibility was reported to the Commission on 6 July 2016.

ii. *Florpyrauxifen benzyl*

Florpyrauxifen benzyl is a herbicide. The RMS is Italy and the applicant is Dow AgroSciences. Admissibility was reported to the Commission on 17 June 2016.

Member States took note of these two new admissible dossiers.

2. European Food Safety Authority (EFSA) conclusions:

There were no recent EFSA Conclusions to report.

3. Commission draft review report and Regulation concerning the (non-) approval of:

i. *Beta-cypermethrin*

The Commission informed Member States that further discussion was ongoing about the next steps and the appropriateness of the initial proposal for approval given the

comments and concerns of Member States in relation to risks to non-target species, in particular non-target arthropods. Member States were asked to further consider their positions given the problems identified.

ii. Pseudozyma flocculosa ATTC 64874

The Commission asked Member States to submit information on the existence of provisional authorisations issued for this active substance for which a proposal of non-approval is under preparation.

iii. Oxathiapiprolin

The Commission seeks to approve this active substance. A short summary of the issues identified in the EFSA Conclusion was given to Member States. One Member State expressed concerns regarding leaching of metabolites to groundwater. Member States were asked to provide their comments by 11th November 2016.

iv. Bacillus amyloliquefaciens FZB24

The Commission proposes to approve this substance as a low risk substance. A short summary of the key issues identified in the EFSA Conclusion was given to Member States. One Member State expressed concerns regarding the proposed low risk status. Member States were asked to provide their comments by 11th November 2016.

v. Cyclaniliprole

The Commission informed Member States on the proposal to not approve the substance due to withdrawal of support by the applicant. A draft proposal uploaded in CIRCABC for comments to be sent to the Commission by 11th November.

vi. Beauveria bassiana strain 147

The Commission informed Member States on the comments received by two Member States and the applicant on the draft review report of March 2016. A revision of the draft review report will be uploaded to CIRCABC as soon as possible. Comments to be sent to the Commission by 11th of November 2016.

vii. Beauveria bassiana NPP111B005

The Commission informed MS on the comments received by two MS and the applicant on the draft review report of March 2016. A new revision of the draft review report will be uploaded to CIRCABC as soon as possible. Comments to be sent to COM by 11th of November.

viii. Orthosulfamuron

The Commission informed Member States that the proposal on not approving the substance will now undergo the final consultation and consultation under the TBT (technical barriers to trade agreement). The Commission intends to present a final draft for vote as soon as the consultation is finalised.

ix. Flutianil

The Commission will proceed with this file as soon as the classification under Regulation (EC) No 1272/2008 is adopted.

4. Withdrawal of application for *Fusarium* sp. strain L13

The applicant for *Fusarium* sp. Strain L13 has informed the Commission on 4th July about the withdrawal of their application for approval and its intention to apply at a later point in time again once the taxonomy of the microorganism is further clarified. The letter of withdrawal has been uploaded on CIRCABC.

As the evaluation process was still in an early phase, there is no need to adopt a formal legal act.

A.03 Renewal of approval:

1. AIR III (Annex I Renewal Projects): State of play

The Commission gave an update on the progress of the AIR III programme of work. It was indicated that due to delays in the assessment of dossiers, several substances would require an extension to their approval. This concerns batches 3 and 4 of the AIR III program where it is foreseen that a decision cannot be taken within the current deadline. Furthermore, two substances, Fipronil and Maneb, will have their expiry dates set back because dossiers were not submitted. It was confirmed that in accordance with Article 17 extensions may be granted only when applications and dossiers are submitted and are being examined.

The draft working document on the Europa website will be updated accordingly.

The Commission also informed Member States about the overall status regarding dRARs for the first four batches of the AIR III programme. The Commission is aware about delays of the renewal assessment reports and has therefore asked some Member States to provide an update on when they expect the dRARs to be finalised. The Commission stressed the importance of keeping the legal timelines and pointed out that this is particularly important for substances that may fail to meet the approval criteria.

The following delays were highlighted and the RMS have provided their expected timeline.

Batch 1:

- All dRARs finalised by RMS.

Batch 2:

- Deltamethrin (RMS UK) dRAR expected January 2017.

- Flufenacet (RMS PL) dRAR expected January 2017.
- Fosthiazate (RMS DE) dRAR expected December 2016.
- Beta-cyfluthrin (RMS DE) dRAR expected January 2017.

Batch 3:

- Pyraclostrobin (RMS DE) dRAR expected April 2017.

Batch 4:

- Quinoxyfen (RMS UK) dRAR expected December 2016.
- Thiacloprid (RMS UK) dRAR expected October 2017.
- Ziram (RMS IT) dRAR ready and about to be sent to EFSA.

2. AIR IV: State of play

The Commission informed that Implementing Decision 2016/C 357/05 on the AIR4 work programme had been adopted on the 28 September 2016.

It was confirmed that the Commission is preparing a regulation to extend the expiry dates for the first batch of substances in the AIR IV programme. Since July 2016, 54 substances had the deadline for application and the Commission is aware of 44 applications for renewals and 3 notifications of non-renewals. To date, 27 applications have been declared admissible. As the Commission only postpones the expiry dates for substances which have received an application an email will be sent out asking MSs to check whether for substances where the Commission is not aware of an application for renewal, Member States have received an application or not.

The Commission also informed Member States about two changes that will be made in the AIR IV work programme. It concerns the active substances Tetraconazole and Malathion that were initially placed in *Group 3 "substances that may fail to meet the approval criteria"*. They will be moved to *Group 4(1) – substances that will be postponed with two years* in order to be consistent and ensure equal treatment for substances with the same properties.

An updated version of the AIR IV work-programme will be uploaded to the Europa website.

3. EFSA conclusions:

i. *Flurtamone*

This item was discussed under item A.03.04.14.

ii. 2,4-DB

The Commission outlined the contents of the EFSA conclusions and the comments hereupon received from the applicant. EFSA concluded that high risks could not be excluded for mammals, non-target arthropods and aquatic organisms, especially aquatic plants. The consumer assessments for products from animal origin could not

be finalised due to the absence of additional metabolism studies. Exposure however is low. A particular point is the revised toxicological endpoints for 2,4-D which here occurs as a metabolite of 2,4-DB. The new values appear as a footnote in the EFSA conclusion for the latter; which is not a perfect situation as regards transparency. The Commission is of the opinion that such revision of the endpoints should be linked to the original 2,4-D conclusion, while also its consequences on the current ARfD, AOEL and ADI should be re-calculated. The review of the 2,4-D endpoints will be dealt with in future as a separate agenda point.

iii. *Coniothyrium minitans* Strain CON/M/91-08

Member States were asked to start considering the Conclusion in anticipation of future discussions at future PAFF meetings.

iv. *Mesotrione*

The Commission briefly referred to the main issues underlined in the EFSA conclusions and brought the attention of the delegates to the uploaded comments recently received by the applicant. A more in depth discussion has been postponed to the next December meeting when draft review report will be available.

v. *Pendimethalin*

The Commission briefly referred to the main issues underlined in the EFSA conclusions and brought the attention of the delegates to the uploaded comments recently received by the applicant. A more in depth discussion has been postponed to the next December meeting when draft review report will be available.

vi. *Silthiofam*

Member States were asked to start considering the Conclusion in anticipation of future discussions at future PAFF meetings.

vii. *Propyzamide*

Member States were asked to start considering the Conclusion in anticipation of future discussions at future PAFF meetings.

4. Draft Review Reports for discussion:

i. *Famoxadone*

This item was not discussed.

ii. *Flumioxazin*

This item was not discussed.

iii. *Flupyrsulfuron-methyl*

Member States were informed that a revised EFSA Conclusion had been published by EFSA due to the oversight during the original peer review of some un-finalised areas related to metabolites. The Commission asked Member States for any comments on this revised Conclusion. The Commission was considering the revisions to see if these would have any impact on overall decision making. Member States were asked for their comments and views on this by 11th November 2016.

Member States were given an update on the ongoing assessments of negligible exposure and Article 4.7. The RMS, France, was finalising the negligible exposure assessment which would be sent to EFSA for peer review. With regards to the Article 4.7 submission, the applicant had submitted a revisied submission taking into account the protocol for herbicide substance published by EFSA in August 2016.

Concerning the protocol, it was also confirmed that work was ongoing on a protocol for insecticides and that the Commission would also request work on a fungicide protocol. Once these were completed, a single document would be prepared and further guidance added based on experience. This single document would be subject to public consultation and further discussion in the PAFF Committee.

Member States were also informed that the applicant had new information available regarding the proposal for classification as reproductive toxicant category 2, which in their view showed no impact on reproduction or fertility. The Commission was considering this but advised that a Harmonised Classification and Labelling (CLH) report should be submitted to ECHA. The information received had been made available to all Member States via CIRCABC.

iv. *Pymetrozine*

The Commission informed Member States about the state of play of the file. The RMS had submitted a Statement to the Commission indicating that they would not perform an assessment of negligible exposure but that for two representative uses the residues are expected to be below 0.01 mg/kg. The Commission mandated EFSA to carry out an assessment of negligible exposure with a deadline of 15th December.

With regards to consideration of serious danger to plant health under Article 4.7 the Commission informed Member States that work had begun in EFSA to establish a protocol for insecticides.

v. *Fenamidone*

Member States were reminded that the key issue precluding renewal of approval was the lack of ability to conclude on the genotoxic potential of the substance. However, given the divergent views expressed by Member States and the applicant on the issue, and in light of other cases whereby genotoxic potential had been inconclusive (for different reasons), the Commission was working on a mandate to EFSA to ask for clarification on a number of aspects related to genotoxicity assessments.

The proposal for non-renewal remains but may be re-considered in light of the mandate. It was hoped that mandate would be finalised and issued to EFSA in the near future.

vi. *Isoxaflutole*

Member States were reminded that a proposal for non-renewal had been made based on the classification as toxic to reproduction category 2 (harmonised) and carcinogen category 2 (proposed). This means that isoxaflutole shall be considered an endocrine disruptor in light of the interim criteria.

Member States were informed that additional information to consider negligible exposure and or Article 4.7 has been requested and received.

The next step was for the RMS to evaluate the information concerning negligible exposure and for EFSA to launch the procedure for Article 4.7.

vii. *Foramsulfuron*

This item was not discussed.

viii. *Linuron*

A revised Regulation and Renewal Report were made available before the meeting and explained.

Comments submitted by the applicant on the renewal report were highlighted in particular comments related to endocrine disrupting potential. The Commission explained that the interim criteria applied and that there were effects seen in mammals, fish and birds in addition.

Comments received by Member States were all supporting the proposal for non-renewal of approval.

The TBT notification had been launched and a vote was foreseen in the December PAFF meeting.

Member States were asked for any final comments by 11th November 2016.

ix. *Iodosulfuron*

Comments were received from several Member States which resulted in minor changes to Renewal Report. Inter-Service consultation will be launched.

x. *Imazamox*

Comments were received from the applicant and several Member States in relation to the Commission proposal for non-renewal of approval based on the unresolved genotoxic potential. The Commission explained that there was ongoing discussion internally on how this issue could be handled and asked for further comments.

xi *Maleic hydrazide*

The first proposal for non-renewal was made based on (a) unresolved toxicity profile of a metabolite and (b) the level of impurity hydrazine in the technical specification which is not supported by the toxicological assessment. A short summary of the applicant's comments was given. Member States were asked to provide their comments by 11th November 2016.

xii. *Picoxystrobin*

The Commission explained that given the number of concerns and issues that could not be finalised highlighted in the EFSA Conclusion that a proposal for non-renewal had been made. The comments of the applicant on the renewal report were made available.

It was mentioned that picoxystrobin would be considered as part of the plan to mandate EFSA on genotoxicity assessments, but that given the others issues identified in a number of areas, including risk to consumers, decision making would not be put on hold.

Member States were informed of a significant number of letters of support that were received since July. These were made available on CIRCABC.

Member States were asked to provide comments on the proposal by 11th November 2016.

xiii. *Cyazofamid*

The Commission informed Member States on the proposal to not approve the substance due to lack of data in several areas of assessment. A draft review report uploaded in CIRCABC for comments to be sent to the Commission by 11th November 2016.

xiv. *Flurtamone*

The Commission explained that the EFSA Conclusion did not reflect the actual or possible risks posed by the substance due to a limited assessment which prevented experts being able to conclude on key endpoints. Therefore, as an exceptional measure, the RMS would revisit the RAR and ensure a full and transparent assessment of the studies in the dossier that would then be subject to further peer-review by EFSA and Member States. No new data would be taken into account, only the dossier submitted initially and any information requested during peer review. Once a revised Conclusion was available discussions concerning possible renewal of approval would continue.

In the meantime, to meet the 6 month period to present a draft Regulation and Renewal Report, these had been prepared concerning non-renewal. These would be reconsidered in light of the amended Conclusion.

Member States were also reminded about the importantance of carrying out high quality, robust and complete assessments.

5. List of studies relied upon in the renewal assessment

Member States were reminded that when acting as Rapporteur Member State, they shall transmit the list of studies relied upon (necessary studies) for the renewal of active substances. According to the newly noted revision of the Guidance Document (GD) of the renewal of national authorisations (see point A.08), this document should be made available shortly after the finalisation of the peer-review of the renewal of an active substance.

A.04 Confirmatory data:

1. *Bifenthrin*

Two problems remain. First the recolonisation of certain species of non-target arthropods in field is not completely established. Secondly, the monitoring study on bioaccumulation/biomagnification would indicate that safe uses have been identified although this would require a high degree of risk mitigation. The options for risk management are an EU restriction on rates (provided this is a realistic scenario), a referral of the matter to Member States when authorisations are sought, or, in the worst case, withdrawal of the substance. The Commission will contact the applicant and give a possibility to provide its position on the outstanding issues.

2. *Thiamethoxam*

Discussion on this point was postponed.

3. *Clothianidin*

Discussion on this point was postponed.

4. *Imidacloprid*

Discussion on this point was postponed.

5. *Oxyfluorfen*

The Commission explained that an inter-service consultation had been launched on the proposal to further restrict the approval of oxyfluorfen to use at a maximum rate of 150 g active per hectare, per year. A summary of comments received since the July meeting was presented, some of which did not favour the proposal.

It was foreseen that following inter-service consultation a TBT notification would be launched and a vote scheduled for early 2017.

6. *Tetraconazole*

The Commission informed that some clarification in writing by RMS Italy has not yet been received. This is acknowledged by the RMS which explains this was due to a technical problem. The matter will be corrected in due course.

7. *Fluquinconazole*

the Commission explained the remaining issue relates to the long term risk to birds (other than insectivorous birds) and mammals. EFSA concludes a high risk cannot be excluded although the values are close to trigger. It must be reflected whether restrictions in timing and number of application might solve the matter. The Commission will contact the applicant and give him the possibility to provide its position.

8. *Metazachlor*

Due to its recent classification as Carc 2, metabolites of metazachlor must be checked on their relevance. Potentially all of them leach above 0.1 µg/l in all scenarios. While it is already established that one metabolites (M12) is not relevant, doubts remain as regards the others. A mandate to EFSA is under preparation on the relevance or not of these metabolites, and on the reliability and representativeness of existing monitoring data. The issue will be back on the agenda once EFSA concluded its evaluation.

9. *Buprofezin*

The Commission summarised the comments received since the July meeting where Member States were asked to comment on the proposal to restrict use of buprofezin to crops that were not subject to industrial processing. Concerns had been raised about whether this approach was protective enough for consumers.

The Commission explained that it was considering the appropriate course of action given the concern identified from exposure to aniline. A possible restriction to non-edible uses was proposed as an alternative to non-approval.

Member States were asked to provide their final comments on their preferred approach by 13th October 2016.

10. *Malathion*

The main issue is the toxicity (including genotoxicity) of several metabolites. It is considered to request the opinion of EFSA in this respect.

11. Tri-allate

While the examination of the submitted confirmatory information allowed to solve several remaining matters (biomagnification in the aquatic food chain, risk to fish-eating mammals, earthworms), the fate and behaviour of one soil metabolite (DIPA (diisopropylamine)) is problematic, due to its poor toxicological database. Hence, this metabolite occurs in groundwater at levels far above the limit of 0.1 µg/l. It also appears above 10% ADI and 10µg/l. Before reflecting on a mandate to EFSA to address other issues (such as plant metabolism and residue definition), MS should reflect whether this metabolite, which is a precursor to nitrosamines, could be possibly considered non-relevant. Member States are invited to comment by 11 November 2016.

12. *Diclofop*

The EFSA Technical Report is not per se unfavourable but concludes that straw containing residues of the substance should not be fed, due to data gaps on the toxicity of certain plant metabolites. This is agreed by RMS France. EFSA does not see the benefit of expert meeting as basic elements are still missing on these metabolites. It seems therefore that, as a risk management decision, the recommendation by EFSA should be taken over. A restriction through regulation might be a bit disproportionate but at least the Review Report should make this clear.

13. *Cyflumetofen*

The Commission reminded the Committee that the Opinion of EFSA would be published by the 31 October. The notifier had recently submitted new documents, which could not be taken into account by the Authority.

14. *Napropamide*

The Commission informed that EFSA disagrees that the aquatic risk can be considered solved, as acceptability on uses would require extensive risk mitigation. In addition, refinements, in the form of Focus Step 4 calculations, have not been submitted while, following the opinion of the experts, this could have been done without difficulties. The Commission underlines that indeed a use should not simply be theoretical acceptable but rather based on realistic scenarios. The dossier will be further discussed but COM cannot exclude that serious restrictions or even a withdrawal are to be envisaged. Member States are invited to comment by 11 November 2016.

15. *Dicamba* (revised review report to be noted)

This point was not discussed as this report has already been noted in an earlier meeting.

16. *Fluroxypyr*

Some minor amendments to the revised review report were made ahead of the meeting and Member States were asked to consider the document again.

The Commission explained that the intention is to amend the approval of fluroxypyr by adding a maximum limit for impurity NMP (which is classified as toxic for reproduction category 1B) to be below 3 g/kg (such that technical material would not be classified). The remainder of the points were considered addressed or could be considered by Member States when carrying out assessments for authorisation.

17. Tall oil pitch

Member States were informed that action was being progressed to withdraw the approval following the failure of the applicant to address the requirements established

in the approval. One Member State had already indicated in writing that they supported the proposal for withdrawal.

Member States were asked for their comments on this proposal by 11th November 2016.

18. Tall oil crude

Member States were informed that action was being progressed to withdraw the approval following the failure of the applicant to address the requirements established in the approval. One Member States had already indicated in writing that they supported the proposal for withdrawal.

Member States were asked for their comments on this proposal by 11th November 2016.

19. Straight chain lepidopteran pheromones (revised review report to be noted)

The Commission briefly explained the changes in the revised review report and asked the Committee to take note of it.

The Committee took note of the revision 12 of the doc. SANCO/2633/2008.

20. *Methyl nonyl ketone* (lack of data submission)

As the applicant failed to submit the requested confirmatory information (due by 31.12.2015) a withdrawal of the substance will be drafted. It may be noted that no application for renewal as an AIR IV substance has been made either.

21. TDM (triazole derivative metabolites) - point added to original agenda

The EFSA Technical Report on this series of metabolites common to the azole family of active substances has been received in August 2016. The Commission is very grateful to RMS United Kingdom which examined this issue which turned out to be very complex due to the number of metabolites concerned, the data gaps in their assessment, and the number of active substances to be considered. It seems necessary to mandate EFSA to explore further certain elements in the sections of toxicology and residues. The Commission explained that it does not expect the RMS United Kingdom to have to reconsider the assessment of each individual azole substance in future. This task should be picked up again by the RMS originally responsible for the assessment of the individual substance.

22. AOB

None.

A.05 Article 21 Reviews:

- *Diflubenzuron* (Draft Review Report for discussion)

The Commission referred to the draft review report and the comments received from the applicant as well as from several Member States. The Committee discussed the concerns raised in those comments. The Commission intends to notify the trading partners of the Union and prepare a draft act for the next Committee meeting.

Thiametoxam (Revised Review Report to be noted)
Clothianidin (Revised Review Report to be noted)
Imidacloprid (Revised Review Report to be noted)

The discussion and possible note-taking for these three review reports was postponed.

A.06 Amendment of the conditions of approval:

1. *Abamectin*

The Commission confirmed that, on the basis of the EFSA conclusion, the conditions of approval of abamectin can be amended, as safe nematicide uses were identified. Some specific provisions as well as confirmatory data should be provided. The notifier was allowed to comment on the draft addendum to the review report. The latter, alongside a draft regulation amending the conditions of approval of abamectin was discussed with Member States. A vote at the next meeting of the Committee is expected.

2. *Fenazaquin*

No update.

3. *8-Hydroxyquinoline*

The Commission confirmed that, on the basis of the recently adopted classification and the EFSA conclusion, an undoing of the current restrictions is not possible. The notifier will however be requested whether the unrestricted representative uses meet the provisions for negligible exposure or article 4.7 of the Regulation.

The current approval cannot be withdrawn as the approval criteria set in Annex II only apply at approval or renewal. Due to the newly adopted classification, 8-hydroxyquinoline will be added on the list of approved active substances for which the products shall undergo a comparative assessment.

4. Acrinathrin

The Commission confirmed that, on the basis of the EFSA conclusion, a revision of the current restrictions is not possible. The aquatic risk is confirmed, its toxicity endpoints remain very low. Increasing rates would even worsen exposure. In addition: consumer intakes are not backed by adequate residue trials at the higher levels. A formal act in the sense of a confirmation of the existing restrictions is ready but not yet internally agreed. It will be proposed for a vote at the next meeting of the

Committee. As regards the practical implementation of the existing rate restriction, the following Member States are kindly invited to report by 11 November 2016 on the situation on their market: Cyprus, Greece, Spain, France, Italy, Portugal, Malta.

A.07 Basic substances:

1. Pilot projects: state of play

No news.

2. New dossiers received:

i. Sea Salt

The Commission received a new application for the approval of sea salt as a basic substance on 21st of July 2016. The Commission will consider this as an extension of the substance salt for which an application is already pending and has asked EFSA to address both applications simultaneously in their technical report.

3. EFSA Technical Reports:

i. *Urtica* spp.

The Commission received the technical report from EFSA on 28th of July.

ii. Hydrogen peroxide

The Commission received the technical report from EFSA on 13th of September.

4. Draft Review Reports for discussion

i *Equisetum arvense* (revised Review Report Rev. 6 for extension of use; to be noted)

The Commission resumed the proposal to extend the approval of the basic substance Equisetum arvense with the use on mulch and refer to comments received from Member States. The Committee took note of revision 6 of the review report.

ii Sodium hydrogen carbonate (revised review report for extension of use; to be noted)

The Commission informed Member States on the proposal to extend the approval of the basic substance sodium hydrogen carbonate with the use as a herbicide on potted plants in greenhouses and the comments received from Member States and the applicant on the draft review report. The PAFF Committee took note of revision 3 of the review report that now includes the extension.

iii Clayed charcoal

The Commission informed Member States on the proposal to approve clayed charcoal as a basic substance. A draft review report uploaded in CIRCABC for comments to be sent to the Commission by 11th November.

iv *Satureja montana L.*

The Commission informed Member States on the proposal not to approve Satureja montana L. essential oil as a basic substance. A draft review report uploaded in CIRCABC for comments to be sent to the Commission by 11th of November.

v *Origanum vulgare L.*

The Commission informed Member States on the proposal not to approve Origanum vulgare L. essential oil as a basic substance. A draft review report uploaded in CIRCABC for comments to be sent to the Commission by 11th of November.

A.08 Exchange of views and possible taking note of the following Guidance Documents:

1. Draft Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (doc. SANCO/13170/2010 Rev. 14.0 to be noted)

The Commission informed Member States on the revision 14 of the Guidance Document (GD). The main amendments focus on simplification and clarification of the interpretation of Article 43. The procedure to allocate the zonal rapporteur Member State was shortened; the data matching step and the specification check were clarified and the timelines in case of missing data were better described. 27 Member States agreed to take note of rev. 14 of this GD. Germany did not wish to take note of the document and provided a detailed list of comments that should be addressed. The Commission and Member States agreed that the GD should be further improved as it is still a new provision and Member States gain regularly experience, which should be taken up into the GD.

The Committee took note of the GD. Germany did not take note of the document.

2. Draft Guidance Document on zonal evaluation and mutual recognition, withdrawal and amendment of authorization under Regulation (EC) No 1107/2009 (doc. SANCO/13169/2010 Rev. 10 to be noted)

The Commission informed Member States on the revision 10 of the Guidance document. The main amendments provide harmonisation for the implementation of Article 34 and simplification for other procedures related to authorisations and zonal assessment. Member States could not agree to take note of rev. 10 of this GD, with comments from Germany, Netherlands and Portugal. The GD will be referred back to the Post Approval Issue Group.

3. Draft Guidance Document on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (Doc. SANTE/10832/2015) (to be noted)

The document was not discussed extensively as the documents were not circulated between Member States before the meeting.

4. Draft Guidance Document on Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414), (Doc. SANCO/3030/99 rev. 5) (for discussion only).

The Commission introduced the draft revision of the GD. The need to amend the guidance related to methods of analysis was agreed and the drafting was led by Germany and France. A first round of comments finalised between phys-chem experts. A second broader round of comments was launched at the Working Group on official formulation labs and PAFF. It also involved consultation with stakeholders. Comments should be sent to France and Germany before the 21 October 2016.

5. Draft template for the data matching check (Doc SANTE/11449/2016) (to be noted)

The Commission introduced the draft template, which is almost identical to appendix I of the Guidance Document on the Procedures Relating to the Authorisation of Plant Protection Products Following the Inclusion of an Existing Active Substance in Annex I of Council Directive 91/414/EEC. Marginal amendments were performed to bring this template in line with the Regulation (EC) n° 1107/2009. Belgium made a comment during the meeting and it was decided to postpone the endorsement of this template to the next PAFF to fully address the comment made.

A.09 Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (to be noted).

15 notifications have been received from Poland, concerning amendments of authorisations of products containing the active substance chlorpyriphos.

The Committee took note of the notifications submitted by Poland.

A.10 Notifications under Article 36(3) of Regulation (EC) No 1107/2009 (to be noted).

Three notifications have been received. For one of them the Commission asked the notifying Member State to provide some clarifications. The two others are related to voluntary mutual recognition and therefore outside of the scope of Article 36(3).

A.11 Notifications under Article 53 of Regulation (EC) No 1107/2009 (to be noted).

Dimethoate (Belgium)
Cyantraniliprole (Belgium)

Ethephon (Belgium)
Iprodione (Estonia)
Quizalofop-P-ethyl (Finland)
Difenacoum (Finland)
Metalaxyl-M/Mefenoxam (France)
Indoxacarb (France)
Profoxydim (France)
Bentazone (France)
Pyrethrins (France)
Pyridalyl (France)
Cyazofamid (France)
Pyraclostrobin/dimethomorph (France)
Asulam (sodium salt) (France)
1,3 dichloropropene (France)
Phenmedipham (France)
Spinosad (France)
Picoxystrobin (France)
Chlorpyrifos-methyl (France)
Dimetomorph/Mancozeb (France)
Lime sulphur (calcium polysulphide) (France)
Azadirachtin (France)
2,4 D (France)
Dimethenamid-P/Metazachlor (France)
Chlorothalonil/Metalaxyl-M (France)
Ethylene (France)
Cymoxanil (France)
Lambda-cyhalothrin (Germany)
Pyrethrins (Germany)
Ethylene (Greece)
Lavandulyl senecioate (Greece)
(Z)-9-Tetradecen-1-yl acetate/(Z)-11-Tetradecen-1-yl acetate (Greece)
Napropamide (Greece)
Propanil (Greece)
Chloropicrin (Greece)
1,3-Dichloropropene (Greece)
Abamectin (aka avermectin) (Greece)
Chlorantraniliprole (Greece)
Fenamiphos (aka phenamiphos) (Greece)
Kieselgur (diatomaceous earth) (Latvia)
Sodium silver thiosulphate (Latvia)
1,3-Dichloropropene (Malta)
Chloropicrin (Malta)
Clomazone (Portugal)
Alpha-cypermethrin (Portugal)
Clothianidin (Portugal)
Acibenzolar-S-methyl (Portugal)
Acepamiprid (Portugal)
6-benzyladenine; 1-napthylacetic acid (Portugal)
Spiromesifen (Portugal)
Propanil (Portugal)

Pyrethrins and of piperonyl butoxide (Portugal)
Paclobutrazol (Portugal)
Pyriproxifen (Portugal)
Fludioxanil (Portugal)
Tricyclazole (Portugal)
Spirotetromat (Portugal)
Bentazone (Portugal)
Azadirachtin (Portugal)
Spinetoram (Portugal)
Thiacloprid (Portugal)
Acetamiprid (Portugal)
Bacillus thuringiensis spp aizawai (Portugal)
Dimethoate (Portugal)
Maleic hydrazide (Portugal)
Spinosad (Portugal)
1,3-dichloropropene (Portugal)
Imidacloprid (Romania)
Clothianidin, beta-cyfluthrin (Romania)
Ipconazole/Imazalil (aka enilconazole) (Sweden)
Spinosad (Sweden)
Ethametsulfuron (Sweden)
Chlorantraniliprole (Sweden)
Metazachlor/Quinmerac (Sweden)
Paraffin oil/(CAS 8042-47-5) (Sweden)
Fatty acids C7-C18 and C18 unsaturated potassium salts (CAS 67701-09-1) (Sweden)
Thiophanate-methyl (Sweden)
Spinosad (United Kingdom)
Thiacloprid (United Kingdom)

The Committee took note of the notifications submitted by Belgium, Estonia, Finland, France, Germany, Greece, Latvia, Malta, Portugal, Sweden and the United Kingdom.

The Commission recalled that under the provisions of Article 53, Member States concerned shall immediately inform the Commission and the other Member States of the measures taken, providing detailed information about the situation and any measures taken to ensure consumer safety.

In addition, the Commission pointed out that even if a Maximum Residue Level (MRL) set under Regulation (EC) No 396/2005 cannot be met and a national MRL is set, a consumer risk assessment needs to be carried out and forwarded to the Commission, the European Food Safety Authority and Member States.

Member States were reminded that they shall put in place the necessary risk mitigation measures to ensure acceptable uses for human and animal health and the environment.

Furthermore, the Commission pointed out that for minor uses Member States should make use, whenever possible, of the provisions laid down in Article 51 of Regulation (EC) No 1107/2009. Member States should also take into account efficacious

alternatives which are available among bio-pesticides and bio-control agents to promote low input techniques as required by Directive 2009/128/EC.

A.12 Notifications under Article 30 of Regulation (EC) No 1107/2009 (to be noted).

A notification by Ireland on the provisional authorisation of cyantraniliprole was uploaded on CIRCABC.

The Committee took note of the notifications submitted by Ireland.

A.13 News from European Food Safety Authority (EFSA).

- EFSA presented the following points regarding ongoing and planned activities:

- Guidance on residue definition. The guidance is finalised and sent to the publishers for publication. EFSA organised an Info session in September, with participants from many Member States, the GD will be presented to the Standing Committee sections – Legislation and Pesticide Residues.

- Meeting of the EFSA P esticide Steering Network is scheduled for February 2017. EFSA is working on a draft proposal following the June 2016 workshop, to be presented at a teleconference before the meeting.

- EFSA updated the Committee on the trilateral meeting Commission-EFSA-ECHA (European Chemicals Agency) held on 4th October regarding the development of harmonised guidance by EFSA and ECHA on the hazard identification for endocrine disrupters, to be applicable to pesticides and biocides.

- Annual monitoring report: has been sent to the publishers and will be published later in October 2016

- Genotoxicity assessment: The Commission is preparing a mandate for EFSA to clarify the genotoxicity assessment. A draft is currently discussed with EFSA. After checking the specific claims from several applicants, EFSA has so far not identified inconsistencies in the genotoxicity assessments of the recent conclusions.

- Classification of active substances: Commission required EFSA to provide more background information in cases EFSA proposes the classification of an active substance for which no harmonised classification exists or where EFS derives from an existing harmonised classification. In particular for classifications adopted under Directive 67/548/EEC, EFSA might need support from the RMS, to clarify the basis for the original proposal. EFSA reminded all Rapporteur Member States (RMS) to submit a proposal on the harmonised classification to ECHA and the RAR/DAR to EFSA according to the procedure discussed at the Pesticides Steering Committee.

- MRL application form should be submitted to EFSA alongside RAR/DAR submission in the following cases:

    i. RMS/APPL proposes change in existing MRL for one of representative uses
    ii. APPL requests for MRL setting for additional uses
    iii. RAR also addresses confirmatory data set following Article.12 MRL review

- APDESK will standardly ask RMS to double check if one of the above mentioned situations is met and thus if an MRL application form is needed or not.

- Article 4(7): EFSA informed that the EFSA Working Group (WG) under the Plant Health Unit has been established and the first meeting is scheduled for next week. The WG composition is based on an expert selection process for experts acting on personal capacity based on their personal expertise, and has not included nomination by Member States. A consultation with Member States experts through the Pesticides Steering Committee is under consideration once a draft methodological proposal is developed by the Working Group.

- Glyphosate:

    i. MRL Article 2 Review launched on 04/10/2016 following the future procedure as pilot case. Member States will be invited to provide Good Agricultural Practices (GAPs)
    ii. Animal health assessment ongoing with Germany as RMS
    iii. ED mandate received and GTF has been invited to submit all info that will then be evaluated by Germany and peer reviewed by EFSA and Member States
    iv. PAD request MEPs glyphosate: for information the letter with the legal rationale will be distributed to EC and Member States.

- EFSA reiterated the need for a general solution regarding the cases where applicants for renewal does not have access to the original Annex I dossier. The experts in the peer review need the detailed summaries of all relevant studies to be considered in the weight of evidence, including studies submitted in the previous dossier.

- Conclusions on the confirmatory data for the risk assessment of bees will be finalised by the deadline (16 October) for clothianidin and imidacloprid, then EFSA will continue with the review.

A.14 News from Directorate General for Health and Food Safety (DG SANTE) Directorate F (former FVO)

1. Workshop Formulation laboratories

The Commission informed on the main outcomes of the workshop held on 22 and 23 September in Bruxelles chaired by Unit F3.

2. Sustainable Use Directive (Directive 2009/128/EC)

The Commission informed on the next meeting of 9 November 2016 which is co-organised by Unit E4 and F3 and will be held in Bruxelles.

A.15 Report from working groups:

1. Plant Protection Products Application Management System (PPPAMS)

An update on recent activities was provided, focussing on the following areas:

- The system itself and the new version which was made live on 30th September;
- Future developments;
- Emergency authorisations;
- Training;
- Data collection exercise.

A newsletter would be issued to Member States and other users in the coming weeks to communicate the key updates.

2. Article 68 Enforcement Working group

The Commission informed the Committee about the main outcome of the workshop held on 21 and 22 September in Bruxelles chaired by Unit F3.

3. Post Approvals Issues group (PAI)

The Group met in September and touched upon various issues. The key decisions are the following: merging of the PAI group with the Interzonal Steering Committee, finalisation of the update of the guidance documents on zonal assessment and renewal of product authorisations to be forwarded to PAFF, clarification on which variants are supported during renewal and that in case of basic substances, the primary use should not be plant protection.

4. Unacceptable co-formulants

The Commission informed that the WG did not meet since the last PAFF in July. Currently, two sets of criteria are discussed: criteria for exclusion of some co-formulants, in line with the criteria for active substances; criteria triggering an assessment of the co-formulants. The co-formulants meeting the first group of criteria (exclusion) could be easily identified and listed up. More work is expected for the second batch.

5. Biopesticides

The Commission informed that the WG did not meet since the last PAFF in July. The proceedings of the workshop held in November 2015 in the Netherlands are available. The work of this WG will address the open points left at the workshop. First meeting will address sensitization (dermal and respiratory) and clearance of micro-organisms. The call for nomination of Member States experts is still valid. There might be a need also for external experts in those fields.

6. Seed treatment

The Commission informed that the WG did not meet since the last PAFF in July. The draft guidance document is still under finalisation, with regards to the ecotoxicology section. It will be circulated to MSs and stakeholders once finalised.

7. Sustainable plant protection experts group NL proposal

The Commission informed Member States of the meeting of the expert group on 3rd October, where the group discussed their new mandate to support and report on the progress of the implementation plan on low-risk product availability and IPM endorsed by the AGRIFISH Council in June. The Commission called upon Member States not yet participating to nominate delegates and in any case to anticipate on future requests for information required for the expert group to report to the PAFF and the Council on the implementation of the plan's recommendations. The next meeting of the group is planned on 21st November.

8. DRAW Setac-Workshops

9. Revised template for the draft Registration Report (dRR9), part 6 (Germany) (to be noted) - point added to original agenda

Germany introduced the draft revised template for the part B3.6 of the dRR which is now in line with the most recent guidance from EFSA on exposure of human beings to pesticides. The revised template was noted, with an implementation date of 1st January 2017.

A.16 OECD

The Commission informed Member States that a small group of documents were opened for comments by the OECD Secretariat.

A.17 Bees:

1. Review of Neonicotinoids – state of play and next steps (no news)
2. Review of Fipronil – state of play and next steps
3. Commission Communications amending Commission Communications (2013/C 95/01-95/02) as regards the effects on bees
4. AOB

Due to reasons out of control of the Commission, the discussion on this agenda point and its sub-points were postponed.

A.18 Court cases.

- T-476/16 – Adama v. Commission – The Commission informed the Members of the Committee about an action for the annulment of Commission Implementing Regulation (EU) 2016/872 of 1 June 2016 concerning the non-renewal of approval of the active substance isoproturon.

- T- 51/15 – PAN v. Commission – Action for the annulment of Commission decision confirming with regard to the request for access to information of PAN Europe of 3 January 2014 in relation with the scientific criteria for endocrine disruptors. The Commission informed the Members of the Committee about the judgment of 20/9/2016.

- T-600/15 - PAN, Bee Life and Unione nazionale associazioni apicoltori italiani (Unaapi) v. Commission - In an Order of the General court of 28 September 2016 the action for the annulment of the approval of sulfoxaflor was declared inadmissible.

A.19 Endocrine disruptors.

There were no new issues since the last discussion on endocrine disruptors in this section of the Standing Committee.

The Commission informed Member States that there will be an extra-meeting of the Standing Committee on this item in November.

A.20 Minor Uses:

The members of the Standing Committee were updated by the EU Minor Uses Coordination Facility (EUMUCF) on the following issues:

The selection process for the Technical Expert has been finalised and the Technical Expert will start work on 1st November 2016. As from 1st November 2016 the EUMUCF will be fully staffed with the coordinator, administrator, IT-expert and the technical expert.

- Currently, the funding of the Coordination Facility has been guaranteed by France, Germany and the Netherlands for the first three years. Already several other Member States have indicated their willingness to contribute to the funding of the Coordination Facility. It is clear that minor uses problems will not all be resolved in three years. A mid-/long-term planning (5-10 years) and a strategy how other Member States can contribute, is in preparation and has been discussed by the EU Minor Uses Steering Group. Several options for financial contributions have been discussed. An equal contribution from each

Member State can be asked independently of other parameters or contributions from Member States according to their population (equal to the voting system in the Standing Committee on Plants, Animals, Food and Feed). The latter option is considered the most feasible option by the Steering Group. Preferably commitment for contributions should be provided for a longer period. However, it was emphasized that these will be voluntary assessed contributions and that there is no legal obligation for Member States to contribute.

- Preferably the EUMUCF should be financed by contributions from Member States only, and that the EUMUCF does not have to rely on contributions from industry and other stakeholders. This also to avoid any conflict of interest.

- Planning: The EUMUCF will prepare by the end of November an explanatory letter addressed to all Member States with a request for a voluntary assessed contribution. Such a letter will be accompanied by the annual report (narrative and financial over the first year of the EUMUCF). A first discussion with Member States can take place in the Standing Comittee in December. This can be followed by a more detailed discussion in the meeting in January.

- The Coordination Facility has to start planning the first Stakeholder Advisory Forum which will be an annual meeting of stakeholders (including representatives of all Member States) at which the work of the Coordination Facility and wider aspects of the Minor Uses Program will be reported, and advice offered on priorities for future work and ways of working. This will also be an opportunity for further discussion on the long-term planning and strategy with other stakeholders. The EUMUCF is planning to organise its Stakeholder Advisory Forum back-to-back with the Standing Committee meeting in January 2017 in Brussels to encourage and facilitate participation of all Member States.

- The first and second Global Minor Use Summit were held in Rome in 2007, respectively in 2012. The Third Global Minor Use Summit (GMUS-3) and the Second Global Minor Use Workshop will be held in Montreal, Quebec, Canada. The EUMUCF takes part in the Organising Committee. The EU should work on a coordinated contribution.

A.21 Interpretation issues:

This point was not discussed.

A.22 Classifications under Regulation (EC) No 1272/2008 / REACH:

There was no update to provide on this standing agenda point at this meeting.

A.23 Glyphosate:

• State of the dossier

The Commission informed the Committee about ongoing assessments in the EU and reports from other regulatory bodies that became available recently. It also reported the outcome of the discussions in the section Pesticide Residues of the Committee on 22/23 September 2016, in particular regarding the residue definition for enforcement. The Commission encouraged Member States to timely respond to EFSA's call for submission of good agricultural practices (GAPs), for the review of the existing MRLs for glyphosate under Article 12 of Regulation (EC) No 396/2005. EFSA informed the Committee about a decision on two requests for public access to documents concerning the raw data of certain studies in the renewal dossier.

• Implementation of the ban of POE tallow amines in products containing glyphosate.

The Commission received information summarising the action taken at national level in response to the ban of the co-formulant POE-tallowamine from plant protection products containing glyphosate from several Member States, following a discussion in the post-approval issues (PAI) group. It invited all other Member States to send such information to the Commission by 11 November 2016.

A.24 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

The Commission prepared a table containing information on draft measures recently voted at the Pesticide Residues section of the Committee that may have an impact on authorisations. The table is available on CIRCABC.

A.25 Phosphonic acid (inorganic metabolite) - assessment of relevance (Germany).

As a follow-up from the last meeting, the Commission had agreed to explore possible solutions for the inadvertent changes in the scope of the groundwater assessment which occurred when the Uniform Principles were transferred from Directive 91/414/EEC to Regulation (EC) 1107/2009.

The Commission will keep Member States informed.

A.26 Proposal on amendment of criteria for the approval of low risk active substances (doc. SANTE/12376/2015).

The Commission informed Member States about the ongoing inter-service consultation. It is expected the proposal will be finalised in the coming weeks and processed within the feedback mechanism for public consultation for one month. It will depend on the outcome of the process but it should be presented for a possible vote at the Committee in December 2016.

A.27 EFSA Opinion on Risks for public health related to the presence of Bacillus cereus and other Bacillus spp. including Bacillus thuringiensis in foodstuffs.

The Commission informed the Member States of the publication of this opinion and of comments received from third parties since publication. All is made available on CIRCABC. Member States were invited to send in comments by 5th November 2016. These comments will be taken into account during the detailed presentation of this Opinion during the next Standing Committee PAFF section Pesticide Residues on 28-29 November.

Feedback from this discussion will be given in the next meeting of this Committee.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance bentazone in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. (Draft Review Report doc. SANTE/12012/2015 Rev. 5).

Vote postponed

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of the active substance diquat, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Draft Review Report SANTE/10396/2016 Rev. 1).

Vote postponed

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance sunflower oil in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Implementing Regulation (EU) No 540/2011. (Draft Review Report doc. SANTE/10875/2016 Rev. 1).

The draft document was presented for vote and was unanimously supported.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products.

Vote postponed

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Notice concerning time-frame for the use of EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees (Apis mellifera, Bombus spp. and solitary bees).

Vote postponed

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance sulfuryl fluoride (Draft Review Report doc.SANCO/10567/2010 Rev. 1).

Vote postponed

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance thiabendazole in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. (Draft Review Report doc. SANTE/10315/2015 Rev. 2)

Vote postponed

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances acetamiprid, benzoic acid, flazasulfuron, mecoprop-P, mepanipyrim, mesosulfuron, propineb, propoxycarbazon, propyzamide, propiconazole, pseudomonas chlororaphis strain: MA 342, pyraclostrobin, quinoxyfen, thiacloprid, thiram, ziram, zoxamide.

The document was presented for vote. Two Member States voted against because the draft Regulation included the substance thiacloprid.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the approval periods of the active substances fipronil and maneb.

The draft document was presented for vote and was unanimously supported.

Vote taken: Favourable opinion.

M.01 New Scientific publications and information submitted by stakeholders.

No new information.

M.02 AOB

No AOB points.

M.03 Date of the next meeting.

The next meeting is foreseen for 6-7 December 2016.