EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 18 MAY 2016 - 19 MAY 2016

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/1a1a857a-2780-4288-8c55-8bf79e39eb5d*

A.01 Summary Report of previous meetings.

The Committee was informed that the report from the December meeting had been published and that the reports from January and March were in progress.

A.02 New active substances:

1. New admissible dossiers to be noted:

i. 1,3-Dichloropropen - no discussion

ii. Mefentrifluconazole

Fungicide, Rapporteur Member State (RMS) is the United Kingdom and the applicant BASF Agro. Admissibility reported to the Commission on 20 April 2016.

iii. Sodium hydrogen carbonate

Fungicide, RMS is Austria and the applicant BIOFA AG. Admissibility reported to the Commission on 26 April 2016.

Member States took note of admissibility for these two substances.

2. European Food Safety Authority (EFSA) conclusions:

- Cyclaniliprole

Member States were made aware of this recently published EFSA Conclusion.

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

i. Reynoutria sacchalinensis extract

The Commission confirmed the intention not to approve this active substance. Comments received since last meeting were made available. A vote is foreseen in October 2016.

ii Isofetamid

The Commission seeks to approve this active substance. The situation regarding residue data for certain commodities was explained. It is considered that this does not impact an unrestricted approval of isofetamid but will impact the setting of Maximum Residue Limits. One Member State made a comment on the Review Report. Comments received since last meeting were made available. A vote is foreseen in July 2016. Member States were requested to provide comments on the new version of the proposal and review report by 10 June 2016.

iii Bacillus amyloliquefaciens strain MBI 600

The Commission confirmed that the inter-service consultation was ongoing and that a vote for approval would be scheduled for July. The revised versions of the Regulation and Review Report were presented to Member States. Comments received since the previous meeting were discussed, in particular relating to the low risk status of the substance. It was confirmed that since the strain has multi-resistance to 6 antibiotics that low risk could not be supported.

A.03 Renewal of approval:

1. Applications for renewal of approval of active substances submitted under Article 14 of Regulation (EU) No 1107/2009 and in accordance with Regulation (EU) No 844/2012 (SANCO/ 10148/2014 Rev. 6) (For information)

No new information to be reported.

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

The Commission updated the meeting on the state of play of AIR 3: Although there was some slight progress since the meeting in March, the Commission is much concerned about the increasing delays in particular on Member States' side. It becomes clear that for a substantial number of dossiers for which the date of submission of the Renewal Assessment Report is over it will become necessary to extend the approval period of the substance, as decision-making within the legal deadline is no longer possible.

The Commission is committed to only extend the approval periods of substances when there is no other choice and urges Member States and EFSA to do their utmost to meet the deadlines set in the legislation.

3. AIR IV: State of play

The Commission will adopt a decision concerning the AIR 4 programme in accordance with Article 18 of Regulation (EC) No 1107/2009. The draft was made available to Member States on CIRCABC. The decision will be adopted following the advisory procedure, so no vote in the Committee is foreseen. The decision concerns the prioritisation of substances which are potentially low risk and of substances which may fall under the cut off criteria (3.6.2 to 3.6.5 and 3.7 of Annex II).

Due to the size of the AIR 4 programme, other substances will need to be postponed. Only after the applicants have sent their applications will the Commission take a decision to extend the approval period.

The Commission is currently going through the first group of substances in the AIR IV programme that consists of 51 substances with expiry date before 30 April 2019. The Commission will provide Member States with a list of the substances where there is no record of an application for renewal within the next couple of weeks. Rapporteur Member States are to check if they have received an application for renewal of the outstanding substances.

Following a question by a Member State, the Commission confirmed that the decision on AIR 4 would not impact the allocation of rapporteurs and co-rapporteurs.

4. EFSA conclusions:

- Fenamidone

A short summary of the critical concerns and issues identified in the EFSA Conclusion was given to Member States. Several Member States expressed the view that they did not agree with the conclusion regarding the unresolved genotoxic potential. Member States were asked for their comments by 10th June 2016.

5. Draft Review Reports for discussion:

i. Thiabendazole

The Commission confirmed the intention to renew approval of this active substance without restriction. Comments received since the last meeting were made available. A vote is foreseen in July 2016.

ii. Cyhalofop-butyl

Comments received since the last meeting were made available. A comment on the GAP (Good Agricultural Practice) table was forwarded to the European Food Safety Authority (EFSA). EFSA is in contact with the applicant to solve the issue. Once the correct GAP table is available it will be possible to proceed with the legislative proposal.

iii. Bentazone

The Commission confirmed the intention to renew approval of this active substance without restriction. Comments received since the last meeting were made available. A vote is foreseen in July 2016. Member States were requested to provide comments on the new version of the proposal and review report by 10 June 2016.

iv. Famoxadone

Comments received since the last meeting were made available. The Commission will further discuss some comments received with the Rapporteur Member State (RMS) and inform the meeting of the outcome of this discussion on July 2016.

v. Diquat

The Commission confirmed the intention not to renew approval of this active substance. Comments received since the last meeting were made available. A vote is foreseen in October 2016. Some Member States expressed their concern on the AOEL set during the peer review. Member States were requested to provide comments by 10 June 2016.

vi. Ethofumesate (AIR3)

The Commission confirmed that the inter-service consultation would be launched in early June and that a vote for approval was planned for July. The revised versions of the Regulation and Review Report were presented to Member States. A summary of comments received was given.

vii Metalaxyl-M

The Commission confirmed the intention not to renew approval of this active substance. Comments received since last meeting were made available. A vote is foreseen in October 2016.

viii Flumioxazine

The Commission informed on the ongoing Article 4 (7) evaluation for this substance. The RMS is currently evaluating a negligible exposure evaluation provided by the applicant for flumioxazine. The Commission informed the meeting that EFSA agreed with the lowering of the ARfD (Acute Reference Dose) proposed by JMPR (Joint FAO/WHO) meeting on Pesticide Residues. This does not influence the outcome of the risk assessment and will be included in the review report.

ix Flupyrsulfuron-methyl

An update on the state of play was provided for the ongoing assessments: negligible exposure and consideration of derogation under Article 4(7). It was explained that the peer-review for the assessment of negligible exposure had been delayed due to the need to ask for a revision of the assessment by the applicant and RMS following an amendment to the general mandate to EFSA. The deadline for EFSA to provide their Conclusion had also been extended.

With regard to the assessment of the claims submitted in accordance with Article 4(7), the methodology for herbicides was being finalised and was subject to commenting by Member States. Once finalised the assessment for flupyrsulfuron-methyl would be progressed.

x Pymetrozine

See update for point ix above in relation to assessment of negligible exposure. With regard to the Article 4(7) submission, this would be dependent on establishing a methodology for insecticides. It is expected that a Working Group will be established by EFSA before summer and a methodology available in autumn.

6. Metaldehyde: change of co-RMS (AT)

Austria informed the meeting about a request for a change of the co rapporteur Member State (co-RMS) for metaldehyde. In Regulation (EU) 2016/183, Germany is designated as co-RMS. In agreement with Germany, Austria would be willing to take over this task.

The Commission will take care of the necessary amendment in the Regulation.

A.04 Confirmatory data:

1. Epoxiconazole (revised review report to be noted)

The Commission explained that the revised report follows as much as possible the EFSA conclusion of June 2015. Some issues cannot be concluded for the time being [TDM (triazole derivative metabolites), enantiomers] while others can be considered satisfactorily addressed. As regards the long-term risk to herbivorous birds, which was close to the trigger, and given the important influence of local conditions, the matter will be further evaluated at national level, when authorisations are sought. As regards the inclusion of one metabolite in the residue definition, it is proposed to reconsider this matter at renewal stage (should renewal be intended by the Applicant).

As regards the question whether the cut off criteria apply, the Commission explained that from a legal point of view this is not the case. Indeed, the assessment of confirmatory information must be considered to form a unit with the original assessment based on Directive 91/414/EEC, and of which the submission of such information was a condition for approval in accordance with its Article 6(1). It must therefore be assumed that the same legal criteria for approval - i.e. those of the Directive - apply in both cases.

That is corroborated by the fact that Article 80 of Regulation (EC) No 1107/2009 provides for the continued application of the Directive for the procedure and the conditions for approval - including requests for confirmatory information - for a series of dossiers which at the time of application of that Regulation were close to finalisation. It would be inconceivable that a similar regime would be denied to substances already duly approved at that time, as was the case for epoxiconazole,

included through Commission Directive 2008/107/EC. Moreover, recital 10 of Regulation (EC) No 1107/2009, states that for active substances already approved, its criteria should be applied at the time of renewal or review of their approval.

That implies that, for the above legal reasons, the Commission's services consider that the criteria for approval laid down in Annex II to Regulation (EC) No 1107/2009 are not of application. It is obvious that the above does not prejudge the possibility to proceed to a review, in which case the procedure defined in Article 21 of the Regulation shall be applied.

The report, including these clarifications, is proposed for note-taking.

2. Bifenthrin

The remaining problem under discussion today is the recolonization or not of NTA in-field, as mentioned by EFSA. The Applicant is suggesting to redo its study which originally had been done at double the maximum intended rate (i.e. 20 g instead of the 10 g/ha currently defended in the dossier). Member States have been requested to verify whether safe uses have been experienced with these low doses but this does not seem to be the case. Meanwhile more information has been received as regards the monitoring exercise on bioaccumulation/biomagnification. The RMS France has come to the conclusion that such risk is acceptable while EFSA sees some shortcomings in the concept. Discussion to be continued.

3. Dodine (revised review report to be noted)

The Commission presented the revision discussed with Member States earlier. There were no new elements in the discussion. The Committee took note of the revised review report.

4. Thiamethoxam

The Commission informed that EFSA published the technical report on 1 April 2016. From the report it is evident that the data submitted are not sufficient to comply with the confirmatory data request of the legislation. The Commission will take appropriate action in accordance with the procedure foreseen in the legislation.

5. Clothianidin

A mandate to organise a peer-review was sent to EFSA in March 2016. The EFSA Conclusions are expected by 15 September 2016.

6. Imidacloprid

As soon as the RMS will finalise its work, the Commission will send a mandate to EFSA in order to ask to organise the peer review. The intention is to discuss the dossier at the same expert meeting of clothianidin. Therefore the deadline proposed for the finalisation of the EFSA Conclusion will be 15 September 2016.

7. Sulfuryl fluoride

The Commission is working on a modification of the current approval in order to provide for further monitoring of the atmospheric concentration of the active substance. Tighter provisions will be added to insure the compliance of food commodities after fumigation of milling buildings.

8. Oxyfluorfen

The Commission is continuing to explore with Member States whether a safe (representative) use exists for aquatic organisms. A firm proposal was expected to be available for the July meeting.

9. Tetraconazole

The necessary clarification in writing from the RMS has not yet been received. The RMS was kindly invited to verify this.

10. Fluquinconazole

Confirmatory information has been requested for residues, including TDM (triazole derivative metabolites) and the endocrine effects on aquatic organisms. Both matters have been considered adequately addressed. There remains however some scientific disagreement in the ecotox field on which a mandate has been sent to EFSA. The latter has now delivered its conclusion and these state that a risk for some bird species and mammals cannot be excluded. Discussion to be continued.

11. Metazachlor

Due to its classification, all metabolites of metazachlor must be checked for their relevance and their potential leaching to groundwater. The EFSA Technical report is awaited and it is not impossible that a formal mandate to EFSA is sent at a later stage. Discussion to be continued.

12. Prochloraz (revised review report to be noted)

No new comments were received from Member States since the last meeting. As regards the remaining points, it was proposed to further clarify the specification at Member State level, possibly with the submission by the Applicant of a new Ames test. Other ecotox issues, linked with the metal complexes of prochloraz, have been adequately addressed. In the past, some Member States raised more general concerns about the possible endocrine effects of this substance. The Commission explained that endocrine disruption is indeed under consideration in this dossier but ought not to be addressed at this point of time. Indeed, endocrine effects, if any, are part of a future set of confirmatory information to be submitted by the Applicant. The Commission understands however, that even with this explanation, some Member States, as a matter of principle, will continue to oppose the substance. As this position will remain unchanged, the Commission can only take note of the position of these Member States and proceed further with the note-taking on the revised report.

13. 1-NAD (revised review report to be noted)

It was agreed that the risk to non-target plants was already adequately addressed but will need mitigation through buffer zones. Also, it is agreed that the long term risk to insectivorous birds needs to be made more robust through the submission of a chronic study. Taking account of a conservative extrapolation from the acute risk a large margin of safety exists and it is reasonable to request that such study is made available at Member State level. The revised review report is proposed for note-taking.

14. 1-NAA (revised report to be noted)

The situation for NAA is identical to NAD in respect to the risk to birds (see above). The revised review report is proposed for note-taking.

15. Buprofezin

The Commission explained that they had received only a single comment since the previous meeting. Further discussions were ongoing about how to proceed and manage the sensitive issue related to aniline exposure. A firmer proposal was expected for the July meeting.

16. Pyridaben (revised review report to be noted)

The Commission presented the revision discussed with Member States earlier. There were no new elements in the discussion. The Committee took note of the revised review report.

17. Malathion

The EFSA Technical Report is available. As the matter is complex, especially for the toxicological point of view, more time is needed for its examination. Discussion to be continued.

18. Tri-allate

The EFSA Technical Report is available but more time is needed for its examination. Discussion to be continued.

19. Diclofop

The EFSA Technical Report is available and the matter does not seem too complex. RMS France concluded to an acceptable risk although straw should not be fed to animals. Discussion to be continued.

20. Cyflumetofen

The Commission informed the Committee that EFSA was mandated to set up a peer-review to address the points left open in the EFSA technical report. The EFSA conclusions are due by the end of October 2016.

21. Napropamide

The EFSA Technical Report is available. There is some disagreement whether the aquatic risk assessment can be considered acceptable. Discussion to be continued.

22. Dicamba (revised review report to be noted)

It seems doubtless that all evaluators, including EFSA, agree that the presence of soil transformation products has been adequately elucidated and that there is no potential for long range transport via air, given the intrinsic characteristics of the compound. However, as to give Member States more time for examination, the Commission proposed to delay the note taking of the revised review report to the next meeting.

23. Fluroxypyr

The Commission introduced the item to the agenda for the first time. A summary of the assessment outcomes was provided and a number of points were elaborated. Member States were asked for comments by 10th June.

24. AOB

None.

A.05 Article 21 Reviews:

- Diflubenzuron

Discussion postponed until the July meeting.

A.06 Amendment of the conditions of approval:

1. Abamectin

The Commission introduced this item to the agenda for the first time. A summary of the assessment outcomes was provided. Member States were asked for comments by 10th June.

2. Fenazaquin

The Commission re-introduced this item in the agenda. Additional data submitted by the applicant were uploaded on CIRCABC for Member States. The Commission will investigate on the possible way forward for this dossier. It highlighted that a draft Regulation confirming the conditions of approval of the active substance was put forward for a vote in the Standing Committee of December 2014. At that time the majority of Member States were not able to support the draft with a positive opinion, therefore the draft Regulation was withdrawn from the vote.

3. 8-Hydroxyquinoline

The Commission introduced this item to the agenda for the first time. A summary of the assessment outcomes was provided, in the view of the recently adopted RAC opinion on the harmonised classification of 8-hydroxyquinolin. Member States were asked for comments by 10th June.

4. Acrinathrin

The Commission is of the opinion that, on the basis of the EFSA conclusion, it is not possible to consider the lifting of the current regulatory restrictions. Indeed, increasing the rates might even increase the exposure of aquatic organisms. In addition: EFSA considered that consumer intakes are not backed anymore by adequate residue trials at the higher levels. Other issues, such as the risk to groundwater by one metabolite, have been correctly addressed. The Commission will propose at the next meeting a more formal act which will confirm the current restrictions.

A.07 Basic substances:

The Commission referred to an application requiring extension of use concerning Equisetum arvense. In compliance with the provisions of Article 23 derogating from Article 7, the Commission would propose to simplify the procedure in case of amendment, not requiring an EFSA technical report. The documentation submitted by the applicant will be made available to Member States together with the potential proposal for amendment of the review report.

The Commission asked Member States to agree on the proposed simplified procedure for amendment of review report for this basic substance. As there were no comments raised, the Commission will circulate the documentation for the next Plants, Animals Food and Feed Committees (PAFF) meeting .

1. Pilot projects: state of play

The Commission informed the Committee that a meeting for the basic expert group would be planned for the second half of 2016.

2. New dossiers received

i. Mustard Powder

The Commission confirmed receipt of an application for this substance.

3. EFSA Technical Reports

i. Sunflower oil

The Commission brought to the attention of the Committee the EFSA conclusions which are pointing to possible presence of high toxic degradation products on crops

and in the environment. The Commission recalled conclusions of assessment carried out for similar substances such as rape seed oil and fatty acids and considering the rate of application of potential uses and its food grade nature, it should be considered for possible approval as a basic substance. Member States to comment by 10 June.

4. Draft Review Reports for discussion

None

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

1. Draft Guidance Document on Semiochemical Active Substances used in Plant Protection Products (doc. SANTE/12815/2014 Rev. 4.6 to be noted)

The Committee took note of the new guidance document SANTE/12815/2014 Rev. 4.6, with the implementation date set as 1 January 2017.

2. Draft Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (doc. SANCO/13170/2010 Rev. 13.4 for discussion only)

The Commission introduced the revision 13.4 of the Guidance Document prepared by the Post Annex Inclusion Group. A summary of the proposed changes to the current version of the guidance document in place was presented. Member States were asked for comments by the 10th June.

3. 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 for discussion only)

The Commission introduced the revision 10 of the Guidance Document prepared by the Post Annex Inclusion Group. A summary of the proposed changes to the current version of the guidance document in place was presented. Member States were asked for comments by the 10th June.

4. 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) (amendment of implementation schedule - discussion and possible note taking)

The Commission introduced revision 2 of the cover note to the Guidance Document on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. A summary of the proposed changes to the current implementation plan of the guidance document in place was presented. Member States provided comments on the way to address the evaluation of the acute non-dietary exposure of humans to plant protection. The document was not noted and Member States were asked for comments by the 10th June.

5. Draft Guidance Document on Rules for Revision of Assessment Reports (doc. SANTE/10180/2013 Rev. 2 for discussion only)

The Commission introduced the revision 2 of the Guidance Document prepared by the Post Annex Inclusion Group. A summary of the proposed changes to the current version of the guidance document in place was presented. Member States were asked for comments by the 10th June.

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

Altogether, 52 notifications have been sent in by Belgium, France, Hungary, Ireland and Slovenia. Most of them concern chlorpyrifos.

One Member State wonders whether there are authorisations of chlorpyrifos in other Member States that should be amended as well, following the recent change of the reference values. Some Member States confirm that such amendments are currently under preparation and notifications will be provided as soon as possible.

One Member State wonders whether all amendments of authorisations have to be notified, as, including minor amendments might drastically increase the number of notifications.

The Commission confirmed that apparently Regulation (EC) No 1107/2009 does not distinguish between minor and major amendments. The Commission, however, agrees that notifying all minor amendments might lead to a huge workload on Member States' side. The Commission recalls that using the Plant Protection Products Application Management System (PPPAMS) will discharge Member States from uploading such notifications in future, in line with the approach taken for notifications according to Article 53 already now.

The Committee took note of 52 notifications, sent by Belgium, France, Hungary, Ireland and Slovenia.

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

Five notifications have been sent in.

The Commission considers that only in two cases the motivation for refusal of mutual recognition is in line with the provisions of Article 36(3). In particular, differences in the efficacy assessment or the lack of use of additional national models seem not to be sufficient to refuse mutual recognition of authorisations of countries of the same zone.

The Committee took note of the two notifications, sent by Germany.

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

1,3-dichloropropene (Belgium)

Ethylene (Belgium)
Flonicamid (Belgium)
1-decanol (Croatia)
Azadirachtin (Croatia)
Captan (Croatia)
Chlorothalonil (Croatia)
Metamitron (Croatia)
Paraffin oil (CAS 97862-82-3)/Copper hydroxide (Croatia)
Potassium hydrogen carbonate (Croatia)
Pyroxsulam (Croatia)
SCLPs (Croatia)
Lime sulphur (Czech Republic)
Asulam (Denmark)
Captan (Denmark)
Dazomet (Denmark)
Rimsulfuron (Denmark)
Abamectin (Estonia)
Aluminium phosphide (Finland)
Captan (Finland)
Chlorantraniliprole (Finland)
Clomazone (Finland)
Metamitron (Finland)
Quinoclamine (Finland)
Spirotetramat (Finland)
Acibenzolar-S-methyl (France)
Aclonifen (France)
Asulam (France)
Azadirachtin (France)
Bacillus firmus I-1582 (France)
Bromoxynil (France)
Chlorantraniliprole (France)
Chlorpropham (France)
Chlorpyrifos-ethyl (France)
Cyantraniliprole (France)
Ethephon (France)
Ethoprophos (France)
Lime sulphur (France)
Metobromuron (France)
Oxadiazon (France)
Pendimethalin (France)
Penoxsulam (France)
Pyrethrins (France)
Spinetoram (France)
Spinosad (France)
Spirotetramat (France)
Tefluthrin (France)
Aluminium potassium sulfate (Germany)
Aureobasidium pullulans (strains DSM 14940 and DSM 14941) (Germany)
Cypermethrin (Germany)
Fenoxycarb (Germany)

Fosthiazate (Germany)
Lambda-Cyhalothrin (Germany)
Lime sulphur (Germany)
Metarhizium brunneum, strain C15 (Germany)
Metobromuron (Germany)
Pepino mosaic virus strain CH2 isolate 1906 (Germany)
Potassium hydrogen carbonate (Germany)
Spinosad (Germany)
Thiram (Germany)
Trichoderma atroviride, strain SC1 (Germany)
Acibenzolar-S-methyl (Greece)
Alpha-Cypermethrin (Greece)
Bentazone (Greece)
Etofenprox (Greece)
MCPA (Greece)
Tau-Fluvalinate (Greece)
Abamectin (Ireland)
Fluopyram (Ireland)
Carbetamide (Latvia)
Clothianidin/beta-Cyfluthrin (Latvia)
Ipsdienol/ (S)-cis-verbenol/ 2-Methyl-3-buten-2-ol (Latvia)
Isoxaben (Latvia)
Propyzamide (Latvia)
Thiamethoxam/Metalaxyl-M/Fludioxonil (Latvia)
Triflusulfuron-methyl (Latvia)
Clothianidin/beta-Cyfluthrin (Lithuania)
Thiamethoxam/Metalaxyl-M/Fludioxonil (Lithuania)
Chlorophacinone (Luxembourg)
1,3-dichloropropene (Portugal)
Imazamox (Portugal)
Oxadiazon (Portugal)
Spinetoram (Portugal)
Spinosad (Portugal)
Cypermethrin (Romania)
Bacillus thuringiensis subsp. Kurstaki, strain ABTS 351 (Romania)
Azoxystrobin/Cyproconazole (Slovakia)
Beauveria bassiana, strain BB1 (Slovakia)
Bifenthrin (Slovakia)
Boscalid/Pyraclostrobin (Slovakia)
Oxyfluorfen (Slovakia)
Potassium hydrogen carbonate (Slovakia)
Potassium salt (Slovakia)
Acequinocyl (Slovenia)
Bifenazate (Slovenia)
1,3-dichloropropene/chloropicrin (Spain)
Aureobasidium pullulans (strains DSM 14940 and DSM 14941) (Spain)
Clethodim (Spain)
Famoxadone/Cymoxanil (Spain)
Fosetyl-Al (Spain)
Lambda-Cyhalothrin (Spain)

Mefenoxam (Metalaxil-M)/Mancozeb (Spain)
Oxadiazon (Spain)
Rescalure (Spain)
SCLPs (Spain)
Tembotrione (Spain)
Flonicamid (Sweden)
Potassium hydrogen carbonate (Sweden)

The Committee took note of the notifications submitted by Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Latvia, Lithuania, Luxembourg, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

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).

Cyantraniliprole (UK)

Ireland indicated that they had granted a provisional authorisation for cyantraniliprole before 14 June 2016

A.13 Sustainable Use Directive (Directive 2009/128/EC):

1. NAP (National Action Plans) Report

The Commission informed the report is still in internal consultation.

2. State of play

A workshop on demonstration farms for IPM (Integrated Pest Management) is going to take place next week 24 and 25 May in Bonn. The Commission thanked Germany for co-organising and hosting the event. It will involve experts from the SUD and C-IPM Eranet research platform as well as some representatives of advisory services in Member States.

A.14 News from European Food Safety Authority (EFSA).

EFSA informed that under the umbrella of the Pesticides Steering Network (PSN), a dedicated tele-meeting with experts nominated by the Member States was planned for 25 May in order to discuss the Member States' comments on the PPR (Plant Protection Products and their Residues) Guidance on the Residue Definition, the comments will be then considered by the PPR Panel. A general Info-session open to all stakeholders will be held on the 26 September 2016.

The next Plenary of the PPR Panel is open to observers and will be held in Brussels on 22-23 June 2016. In addition EFSA is organising a Scientific Conference on 15-16 November on the Environmental Risk Assessment of Pesticides in Parma and an EFSA-OECD workshop on neurodevelopmental toxicity on 18-19 October in Brussels.

The next PSN Meeting will take place on 14-15 June 2016. The main agenda point is brainstorming on how to make the peer review more efficient and how to enhance collaboration with Member States. Member States are invited to provide agenda items/case studies/specific examples where collaboration can be improved.

Regarding the applicability of the EFSA OPEX guidance and its implementation, EFSA clarified that the acute AOEL and the lack of higher tier scenarios for bystanders and residents should be considered independently. EFSA reiterated its view that following the discussion with the Member States experts at the peer review meetings, the current scientific knowledge is sufficient for allowing the experts to set the acute AOEL or to conclude that it is not needed based on the toxicological profile of the substance. Thus, EFSA proposes the RMS to present a proposal for acute AOEL in all cases, and considers that the lack of specific guidance for setting the acute AOEL is no longer an obstacle for the implementation of the OPEX guidance; the experience from the case-by-case discussions could allow the development of specific guidance in the future if needed. Regarding the scenarios, EFSA requested clarification, not only for EFSA but also for the applicants and RMSs, regarding the scenarios to be used in the risk assessment for bystanders and residents. EFSA considers that despite the limitations and data gaps identified in the OPEX guidance, the application of the EFSA guidance scenarios for bystanders and residents would in any case represent a clear improvement regarding the current system. This view was supported by several Member States. When needed, risk management measures or ad-hoc higher tier refinements can be proposed by the applicants and discussed by the RMS. EFSA can provide support to the RMS if requested.

EFSA informed that following the PSN March meeting dedicated to the Article4 (7) procedure, the EFSA Working Group (WG) is revising the methodology for herbicides and the Member States commenting on the protocol will be launched very

soon. Once the methodology is agreed and finalised, the work on flumioxazin and flupyrsulfuron-methyl will resume and Member States will be invited to submit their claims in line with the protocol and the provided template.

Regarding the assessment of negligible exposure, during the finalisation stage of the EFSA conclusion on flupyrsulfuron-methyl, further discussions took place between the Commission and EFSA and it was decided to put the finalisation of the EFSA conclusion on hold. The Commission invited the APPL to provide further data and risk mitigation measures, the RMS will evaluate these data and afterwards the EFSA peer review will resume. For the same reason, the negligible exposure evaluation of pymetrozine is on hold.

EFSA reiterated the need for getting additional clarity regarding the approval criteria, data requirements and applicable guidance for dossiers submitted for amendment of approval conditions, in particular when the previous evaluation was conducted under a different regulatory frame and/or data requirements.

Regarding the differences in the classification of flutianil proposed in the EFSA Conclusion and the harmonised classification recently proposed by the ECHA (European Chemicals Agency) Risk Assessment Committee (RAC), EFSA informed that is currently discussing the situation with ECHA; if a divergence in scientific opinions is observed, a joint statement will be produced according to the regulatory schemes applicable to EFSA and ECHA; nevertheless, the difference could also be related to additional information submitted during the ECHA process. EFSA reiterated the joint view of EFSA and ECHA, supported by the Commission, requesting the RMS to submit in parallel, according to the alignment procedure, the proposals for harmonised classification to ECHA and the DAR/RAR (Draft Assessment Report/Risk Assessment Report) to EFSA in order to allow the RAC opinion to be considered during the EFSA process.

A.15 News from Food and Veterinary Office (FVO).

The Commission brought to the attention of Member States the uploaded final report of the FVO (Food and Veterinary Office) on "Implementation of the authorisation requirements of Regulation (EC) No1107/2009" analysis based on a survey questionnaire sent to Member States in 2015 of which the main outcome had been presented by the FVO in the Committee meeting of March 2016. The Commission asked Member States to analyse the results in the report and to reallocate resources on national level on order to work off existing delays as quickly as possible.

A.16 Report from working groups:

1. Plant Protection Products Application Management System (Authorisation database) - PPPAMS

An update on the key activities and ongoing developments was given by the Commission, covering the work on development, data collection and training. Some improvements were being completed and would go live on 1st June in order to

facilitate the submission and processing of applications for emergency authorisation. The Commission reminded Member States that all applications for emergency authorisation submitted from 1 June 2016 are to be submitted and processed via PPPAMS. Some Member States were concerned about resources but the Commission explained that the process was simply for emergency authorisations. Feedback on experience would be discussed at the July meeting.

The Commission explained that the online help facility in PPPAMS had been updated and that further training via webinars (for Member States and industry) was being considered.

2. Article 68 Enforcement Working group

On 13 and 14 April the first workshop of this expert group has been chaired in Brussels by FVO. Good participation from 16 Member States, constructive exchange with first step objective to propose a template for reporting results of enforcement under Article 68 of Regulation (EC) No 1107/2009 by the end of this year. It has been decided to finalise the template in another meeting to be held on 21 September close to the Formulation labs workshop which should take place on 22 and 23 September. Final arrangements will be communicated in July. A specific folder has been made available in CIRCABC under Library of PPP named Article 68 expert group. Presentations and documents circulated will be saved there.

3. Post Approvals Issues group (PAI)

During the last meeting in March, the Guidance Documents (GDs) on renewal, on authorisations, on amendment of DARs and RARs were finalised and referred to the Standing Committee. 2,4-D and its variants were discussed as the renewal dossier (and the end-points set based on it) referred only to 2.4-D and renewal dossiers for products authorisations of 2.4-D variants are notified. The PAI group also agreed that a harmonised solution should be designed to solve the issue of Acute AOEL, for product assessments.

4. Unacceptable co-formulants

The Working Group on Unacceptable Co-formulants has proposed a finalised Thought Starter laying down a step-wise approach for the identification of unacceptable co-formulants. The final version of the Thought Starter is uploaded on CIRCABC. The first tier (tier1) identifies co-formulants which are classified (harmonised or self-classified) as CMR 1A or 1B, POP, PBT compounds. As their hazards are of concern, the WG proposed that no voluntary use should be tolerated. The chemicals restricted or specifically authorised according to REACH fall also into tier 1 where relevant to PPP formulations. Tier 2 candidates are also identified by the classification and would trigger a risk assessment performed by a Rapporteur Member State and peer-reviewed. Tier-3 candidates would be identified through other kind of information. They would be also assessed.

Member States were asked by the Commission to notify co-formulants banned at national level or candidates to be listed up on Annex III.

5. Biopesticides

No news since last PAFF Committee. The next meeting will be dedicated to the drafting of a new DAR/RAR template for Micro-organisms.

6. Sustainable plant protection experts group the Netherlands' proposal

The Commission informed the Standing Committee on the state of play of the Expert Group on Sustainable Plant Protection. This group consisted of 19 Member States and Norway, EFSA and the Commission. The Group finalised their implementation plan on increasing low-risk product availability and accelerating IPM implementation during their last meeting on May 11 (document uploaded to CIRCABC). Three specific points are still to be finalised in week 21 (highlighted in the text). The Commission thanked the members of the Expert Group for their input. The Netherlands expressed their satisfaction with the progress made and explained that the Presidency will send the implementation plan as annex to a note to the AGRIFISH-Council of June 27/28 2016. In this note they intend to invite the Member States and the Commission to express their support and commitment for the implementation plan. The Netherlands asked Member States to inform their ministers in preparation of the Council meeting. The Netherlands is considering supporting the Commission with resources for the follow-up of the implementation plan. SK expressed their willingness to continue the Expert Group during their upcoming Presidency.

7. DRAW Setac-Workshops

Postponed.

A.17 OECD

The Commission recalls the 31st meeting of the Working Group on Pesticides that will take place on 30 June / 1 July in Paris. During that week a meeting of the Expert Group on Exchange of Pesticide Data and a meeting and seminar of the Biopesticides Steering Group will take place as well.

A.18 Bees:

1. Review of Neonicotinoids – state of play and next steps

No news.

2. Review of Fipronil – state of play and next steps

No news.

3. Follow-up of information received by an NGO as regards the emergency authorisations granted for neonicotinoids in accordance with Article 53 of Regulation (EC) No 1107/2009

Information received by NGOs including scientific publications was uploaded in CIRCABC for Member States.

4. Follow-up EFSA Conclusions on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam, clothianidin and imidacloprid considering all uses other than seed treatments and granules.

The Commission received comments from a Member State (Belgium) on this topic. The comments are uploaded in CIRCABC. Directorate General for Health and Food Safety (DG SANTE) is of the opinion that no changes should be made to the current conditions of approval of the three neonicotinoids at this stage. The Commission announced that the revised review report reflecting this position and including the reference to the EFSA conclusions, will be circulated soon for comments to Member States.

5. AOB

No.

A.19 Court cases :

Cases C-442/14 and C-673/13: Opinions of the Advocate General.

The 2 cases concern the protection of confidential information in applications for approval of active substances or for authorisation of plant protection products. Case C-673/13 concerns the Volume 4 of the DAR and C-442/14 concern studies submitted to the NL competent authorities.

A hearing took place. The judgment is still pending but the opinions of the Advocate General were published on 14/4/2016.

According to the Commission's understanding, the Advocate General argues that the provisions of the Aarhus Directive and Regulation should be read in a way that it is compatible with Article 63(2) of Regulation (EC) No 1107/2009.

A.20 Endocrine disruptors:

1. Impact assessment

The impact assessment, now at its very final stage, is expected to be published before the summer break, together with the two draft measures containing the criteria for the Plant Protection Products and the Biocidal Products.

Following a question by a Member State, the Commission confirmed that it decided to complete the nearly finalized impact assessment to allow the Commissioners' College, the Member States and the Parliament to take an informed decision on the criteria.

2. Next steps: draft criteria

Two separate draft measures (for Plant Protection Products and Biocidal Products) will first be endorsed simultaneously by the College, published and then will need to be adopted under their relevant procedures (PRAC and Delegated Act).

The Commission informed that on 12 May 2016, the President of the European Parliament received a motion of censure on the Commission signed by a (sufficient) number of Members of the Parliament.

Post-meeting note: It became later clear that some MEPs withdrew their signature and the motion of censure therefore lapsed.

A.21 Minor Uses:

- State of play

The Committee was updated by a presentation from the EU Minor Uses Coordination Facility.

As the first grant agreement ended on 14 April 2016, the EU Minor Uses Coordination Facility (EUMUCF) will now prepare a Final Narrative Report and Final Financial Report covering the first year. Meanwhile the Commission has awarded a grant for the second year of the EUMUCF.

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. At 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, will be prepared.

An advert for a Technical Expert for the EUMUCF has been published on the minor uses website. The deadline for applications is 30 May 2016.

The Terms of Reference of the Commodity Expert Groups (CEGs) and of the Horizontal Expert Group (HEG) have been approved by the Steering Group. The Steering Group has prepared its Terms of Procedure.

Meetings of all the CEGs and HEG were organised back-to-back from 25-27 April 2016 in Brussels. The EUMUCF took care of the organisation and launched a Minor Uses Extranet to facilitate the work of the Expert Groups. The meetings were attended by around 100 people from 20 different countries.

The C-IPM Eranet project from the first call ‘Soil borne pests and diseases’ has been awarded. This project aims to improve the knowledge of relationship between the crop and its pests, as well as the pests and their antagonists and/or natural enemies. Project proposals for the second call have been launched. For more details: http://c-ipm.org/

Different interpretations and approaches taken by Member States in applying Comparative Assessment were highlighted.

Member States supported the use of residue data generated outside the EU, and when scientifically valid, in granting minor uses extensions.

A.22 Interpretation issues:

1. Scope of Regulation (EC) No 1107/2009

No issues.

2. Questions and answers

No new questions or answers.

A.23 Classifications under Regulation (EC) No 1272/2008:

1. Status of harmonised classifications

An updated table on the status of harmonised classifications was made available on CIRCABC.

2. Preparation of Harmonised Classification and Labelling dossiers (CLH dossiers) by Member States and amendment of the format of Draft Assessment report (DAR) and Risk Assessment Report (RAR)

The Commission welcomes the efforts of EFSA and ECHA to lead in developing a new DAR and RAR format which entails a CLH report in the format as requested by ECHA. This is expected to promote the necessary alignment of the risk assessment in EFSA and the classification process in ECHA and shall assure that an EFSA conclusion and an opinion of the ECHA Risk Assessment Committee are available at the same time and can be taken into account by the Commission when preparing a draft for the approval or non-approval of an active substance.

The Commission also reiterates that Member States should prepare a CLH report for all active substances which are not microorganisms or low risk substances.

At the same time, the Commission reminds EFSA and ECHA to assure that their proposal for amendment of the DAR and RAR format shall also include a proposal for the necessary amendments of the pertinent EU and OECD guidance.

A.24 Glyphosate:

- State of the dossier

See agenda item B.06.

A.25 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations (no new meeting has taken place since March 2016).

No news.

A.26 Tefluthrin - Article 56 submission by Syngenta (Germany).

One Member State had submitted written comments which were not made available on CIRCABC. In order to allow a thorough and informed discussion, the point was postponed to the next meeting and Member States were asked to submit possible comments ahead of the meeting.

A.27 Phosphonic acid (inorganic metabolite) - assessment of relevance (Germany)

Discussion postponed.

A.28 Straight Chain Lepidopteran Pheromones (SCLP) : new specifications for a blend amended review report (SANCO/2633/2008 Rev. 11 to be noted).

The Committee took note of the revised review Report.

A.29 Follow up to the workshop on harmonisation of risk assessment in section toxicology held in Vienna in June 2015.

Member States were informed that it will not be possible to hold a follow-up event in 2016 due to lack of resources in Member States. It seems likely that a follow-up would be possible in 2017.

A.30 Question from Denmark and Post Approval Issues (PAI) regarding the implementation of Acute Acceptable Operator Exposure Level (AAOEL).

See Point A 8.03.

A.31 Use of products containing 6-Benzyladine for sprouted seeds.

The Commission wished to share with the Committee a letter of the European Sprouted Seeds Association. It appears that although the products containing 6-Benzyladine are not authorised for use in sprouted seeds, it seems that there is some illegal use. This poses problems of unfair competition. Controlling the use of the products containing this substance in the sector of sprouted seeds is needed.

A.32 Discussion on amending the criteria for the approval of low risk active substances (doc. SANTE/12376/2015).

The Commission brought to the attention of the Committee the proposal and comments received by Denmark. It is the intention to present it for vote in July meeting. Member States to comment by 10 June 2016.

A.33 Information about a Commission Proposal for a Regulation of the European Parliament and of the Council laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 adopted by the Commission on 17.3.2016 (COM(2016) 157 final)

The Commission brought to the attention of the Committee their proposal to amend the provisions for CE fertilisers. The Committee was also given a presentation on the proposed amendment contained in the Commission proposal to clarify the scope of Regulation (EC) 1107/2009 when it comes to biostimulants and plant strengtheners. The discussion is on-going now at the Council of the European Union and the European Parliament.

A.34 Dimethoate: notifications by France according to Art. 21 and 71 of Regulation (EU) 1107/2009.

No new information concerning dimethoate was provided by France.

B.01 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 2,4-DB, beta-cyfluthrin, carfentrazone ethyl, Coniothyrium minitans Strain CON/M/91-08 (DSM 9660), cyazofamid, deltamethrin, dimethenamid-P, ethofumesate, fenamidone, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mesotrione, oxasulfuron, pendimethalin, picoxystrobin, silthiofam and trifloxystrobin.

The draft was presented for vote.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of the active substance cyantraniliprole, 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 doc. SANTE/00111/2015 Rev. 1)

Vote postponed

B.03 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.

The Commission introduced the draft and presented its contents. Member States expressed their positions on the draft. To facilitate further discussions, the Commission invited Member States to submit written comments by 10 June 2016.

Vote postponed

B.04 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).

The Commission introduced the draft and presented its contents. Member States expressed their positions on the draft. To facilitate further discussions, the Commission invited Member States to submit written comments by 10 June 2016.

Vote postponed

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance thifensulfuron methyl 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report doc. SANTE/10150/2016 Rev. 1)

The internal consultation on the draft was not finalised. Therefore the vote was postponed.

Vote postponed

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance glyphosate 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/10027/2016 Rev. 3)

The Commission introduced the revised draft and presented its contents. It referred to feedback received from Member States in response to its invitation at the Committee meeting of 07/08 March 2016, and explained how that feedback has been considered and addressed in the revised draft. Member States expressed their positions on the revised draft.

The Committee discussed possible scenarios regarding the next steps. The Commission invited Member States to submit written comments by 24 May 2016.

Vote postponed

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the low-risk active substance *Saccharomyces cerevisiae* LAS02 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/12457/2015)

The Commission introduced the draft and presented its contents. Member States expressed their positions on the draft.

One Member State abstained because they do not consider that Saccharomyces cerevisiae strain LAS02 met the criteria to be approved as a low-risk substance.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance picolinafen 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/12455/2015)

The Commission introduced the draft and presented its contents. Member States expressed their positions on the draft. To facilitate further discussions, the Commission invited Member States to submit written comments by 10 June 2016.

Vote postponed

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of the active substance beta-cypermethrin, 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 doc. SANTE/12481/2015 Rev. 3)

The Commission introduced the draft and presented its contents. Member States expressed their positions on the draft. The Commission would reflect and consider the comments received.

Vote postponed

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the low-risk active substance Trichoderma atroviride SC1 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/10389/2016 Rev. 1)

The draft was presented for vote.

Vote taken: Favourable opinion.

M.01 New Scientific publications.

No new publications to be referred to the Committee.

M.02 AOB

1. ECPA letter non target plants

The European Crop Protection Association (ECPA sent a letter concerning the EFSA Scientific Opinion on addressing the state of the science on risk assessment of plant protection products for non-target terrestrial plants. It was uploaded on CIRCABC for information of the Committee.

2. Draft guidance photodegradation (Germany)

Germany is currently drafting a guideline for photodegradation, based on a position paper circulated in 2015. Member States are invited to comment in writing.

3. Review of Regulation (EC) No 1107/2009 (United Kingdom)

The United Kingdom asks for an update about the review of Regulation (EC) No 1107/2009 according to Article 82.

The Commission recalls that this review became a part of the REFIT programme of the Commission. A roadmap is currently under finalisation. If there is no unforeseen delay in the further process, the review exercise will start in 2017 with a consultation of all relevant stakeholders.

M.03 Date of the next meeting.

The date of the next meeting was confirmed as 11-12 July 2016.