EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

sante.ddg2.g.5(2016)6214534

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 11 JULY 2016 - 12 JULY 2016

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/34a81b60-2065-456d-990d-e935dd392220*

A.01 Summary Report of previous meetings.

The reports of the meetings on 7/8 March and 27/28 June 2016 have been published.

A.02 New active substances:

1. New admissible dossiers to be noted:

i. ABE IT56

ABE IT56 is a fungicide, the Rapporteur Member State (RMS) is France and the applicant is Staphyt. Admissibility was reported to the Commission on 27 May 2016. One Member State objected because of differing names of the dossier (ABE IT45 and ABE IT56). The Commission clarified it was a typo in the information sheet and the correct name is ABE IT-56.

ii. Pydiflumetofen

Pydiflumetofen is a fungicide, the RMS is France and the applicant is Syngenta. Admissibility was reported to the Commission on 2 June 2016.

iii. Pasteuria nishizawae Pn1

Pasteuria Nishizawae Pn1 is a nematicide. The RMS is Denmark and the applicant Syngenta. Admissibility was reported to the Commission on 3 July 2015.

iv. Ferric pyrophosphate - *point added to original agenda*

Ferric pyrophosphate is a molluscicide. The RMS is Poland and the applicant BROS. Admissibility was reported to the Commission on 24 June 2016.

2. European Food Safety Authority (EFSA) conclusions:

No news.

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

i. Reynoutria sacchalinensis extract - *removed from agenda*

Following 2 points added to the agenda:

ii. Beta-cypermethrin

In the May meeting it was clear that several Member States had strong reservations about the proposal for approval, especially related to the risk to non-target arthropods. The RMS had considered some further comments submitted by the applicant and provided some comments to the Commission. Member States were asked to consider these comments and provide feedback to the Commission on their positions by 19th August.

iii. Pseudozyma flocculosa ATTC 64874

The Commission informed Member States on the proposal to not approve the substance due to lack of data in several areas of assessment and in particular on the human health risk assessment. A draft review report uploaded in CIRCABC for comments to be sent to the Commission by 19th August.

A.03 Renewal of approval:

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

The Commission gave a short update on the progress of the AIR III project. Extension of approval of the first two batches of substances became necessary in the past because of some delays in the process. However, since then the review went more smoothly. In terms of timelines, the first two batches seem to be on track, if no unforeseen delays occur.

This is unfortunately not the case for batches 3 and 4. Here, some substantial delays can be seen in the submission of the dRARs (draft renewal assessment reports), which make it unlikely that there will be sufficient time to finalise the renewal process in time before the expiry of the initial approval. As at earlier meetings of the Committee, the Commission urges Member States to do their utmost to stick with the legal timelines, as the Commission will be obliged to extend the approval period in case of delays that are not under control of the applicants.

A new version of the draft working document on AIR III renewal was uploaded on CIRCABC (Rev. 15). The Commission outlined the changes made in comparison with Rev. 14.

2. AIR IV: State of play

The Commission informed Member States that the document outlining the AIR IV work program with the proposed new expiry dates will be publicly available and uploaded to the Europa website after the meeting. The Commission thanked all Member States who responded to the request at the last meeting confirming which substances with expiry date before 30 April 2019 had received an application for renewal or not. The Commission explained that the AIR IV work programme is needed to even out the workload in the coming years because most of the substances included in the AIR IV renewal program expire in 2019 and 2021. The AIR IV work programme gives priority to presumed low-risk substances and substances that are expected to fail to meet the approval criteria set out in Annex II to Regulation (EC) No 1107/2009. This has been done by dividing substances into four groups. Group 1 consists of substances with expiry dates before 30 April 2019. The application date for renewal has already passed and the substances will not be postponed. The dossier submission is due this fall. Group 2 consists of presumed low-risk substances. They are prioritised because low-risk substances benefit from longer data protection and faster market access which is an important aspect in the promotion of the sustainable use of pesticides. EFSA is also not required to prepare a conclusion and this will hopefully contribute to reduced evaluation time, however, the Commission is aware that due to data-gaps this may not always be the case. The initial aim was not to postpone these substances, however, many substances expire in 2019 and therefore the Commission proposes to extend the expiry dates by one year. Group 3 consists of substances that may fail to meet the approval criteria, i.e., substances that are suspected to be endocrine disruptors or classified as R2 and C2. These substances will not be postponed. Group 4 includes all other substances and the Commission proposes to postpone these by two or three years. The Commission stresses that the application for renewal must be submitted three years before their current deadline. Only when an application is received will the Commission prepare a Regulation and extend the current approval period. If an application is not received, the current expiry date will remain.

3. EFSA conclusions:

i. Linuron

See A.03.4.xii below.

Following points added to the agenda:

ii. Flurtamone

The EFSA conclusion was adopted on 6th June.

iii. 2,4-DB

The Commission informed that the EFSA conclusion has been received on 13 May 2016 and that there are several links to the 2,4-D dossier (common metabolites, Good Agricultural Practices (GAPs) etc.) Next step is the consultation of the Applicant on the EFSA conclusion. Issues at stake are the aquatic risk, the risk to mammals and soil macro-organisms, as well as the consumer intake from commodities of animal origin.

The Commission further underlines that on the basis of this dossier, EFSA indicated it might be necessary to amend the reference toxicological values of 2,4-D.

iv. Coniothyrium minitans Strain CON/M/91-08

The EFSA conclusion was adopted on 8th July.

v. Mesotrione

The Commission informed on the EFSA conclusions received in March 2016 and on comments by applicant available in CIRCABC. Currently the Commission is examining documentation and a proposal will be made in due course.

vi. Pendimethalin

The Commission informed on the EFSA conclusions received in March 2016 and on comments received by applicants available in CIRCABC. Currently the Commission is examining documentation and a proposal will be made in due course.

vii. Picoxystrobin

The Commission gave a short overview of the EFSA Conclusion, highlighting the large number of critical concerns and areas that could not be finalised. The Commission explained that they were carefully examining the Conclusion and comments from the applicant and would make a proposal in due course.

Member States were asked to consider the EFSA Conclusion in preparation for discussion in future Committee meetings.

4. Draft Review Reports for discussion:

i. Cyhalofop-butyl

The Commission explained the small modification in the Good Agricultural Practice (GAP) table. The Inter-Service consultation will now be launched for this dossier.

ii. Bentazone

The Commission explained why this substance is no longer proposed to be included in the Annex for candidates for substitution. The draft review report and proposal were amended as such. Inter-Service consultation will now be launched for this dossier.

iii. Famoxadone

The RMS made an updated worker exposure risk calculation available. The Commission explained that the current proposal for non-renewal of this active substance was kept given the other critical areas of concern identified in the EFSA conclusion. Member States were requested to send comments on the revised worker

exposure assessment and the long term risk to birds and mammals by 19th August 2016.

iv. Diquat

Further comments were received from the applicant and several Member States. The Committee explained that the discussion on an agreed endpoint during the peer review process will not be re-opened during this procedure. The Commission will send out a Technical Barriers to Trade (TBT) notification for the non-renewal of this active substance.

v. Metalaxyl-M - r emoved from agenda

vi. Flumioxazin

The RMS made an evaluation of the negligible exposure calculation available. The Commission requested from the RMS a clarification on the use of the AAOEL (acceptable acute operator exposure level). Once this clarification is received, the evaluation will be forwarded to the EFSA to start the peer review process.

vii. Flupyrsulfuron-methyl

A short update on the state of play was provided.

viii. Pymetrozine

A short update on the state of play was provided.

ix. Fenamidone

The Commission gave an update following the May meeting. A number of Member States had submitted written comments in relation to the critical issue of the genotoxic potential and the setting of reference values. There was a clear divide in opinion between Member States on the issue and how it could be handled. The Commission asked for further comments by 19th August and also explained that there was ongoing discussion internally on this issue.

The first proposal was tabled for non-renewal of approval, based on the issues identified.

The Commission made Member States aware of a large number of letters of support from growers in a range of Member States.

Further discussion would continue in the next meeting.

x. Isoxaflutole

A first proposal for non-renewal was made based on the triggering of the interim criteria for endocrine disruption (classification as reproductive toxicant category 2 and proposed to be classified as carcinogen category). The Commission was further

exploring the next steps including a request for additional information to address negligible exposure and Article 4(7).

It was considered that the risk to groundwater could be addressed by restrictions or mitigation as it was relevant to soils with a pH above 7 and not for all soil types.

The risk to mammals also has to be considered.

Comments were requested from Member States by 19th August.

xi. Foramsulfuron

The Commission seeks to renew the approval of this active substance. A short summary of the critical concerns and issues identified in the EFSA Conclusion was given to Member States. Member States were asked to provide their comments by 19th August 2016.

xii. Linuron

A summary of the key issues identified in the EFSA Conclusion was provided. Several of the concerns were linked to the harmonised classification of linuron as reproductive toxicant category 1B and carcinogen category 2.

There were also a large number of critical issues related to the risk assessments inducing a high risk to residents and to workers from hand-held uses.

The comments of the applicant on the EFSA Conclusion were made available prior to the meeting.

Given the number of concerns identified a non-renewal must be proposed. The Commission asked Member States for their comments and positions by 19th August.

Following 2 points added to the agenda:

xiii. Iodosulfuron

The Commission seeks to renew the approval of this active substance. A short summary of the critical concerns and issues identified in the EFSA Conclusion was given to Member States. Member States were asked to provide their comments by 19th August 2016.

xiv. Imazamox

The Commission expressed the intention not to renew the approval of this active substance. A short summary of the critical concerns and issues identified in the EFSA Conclusion was given to Member States. One Member State expressed concerns regarding impact of the unresolved genotoxic potential on decision making. Member States were asked to provide their comments by 19th August 2016.

A.04 Confirmatory data:

1. Epoxiconazole (revised review report to be noted)

Removed from the Agenda.

2. Bifenthrin

Not discussed.

3. Thiamethoxam (revised review report)

The Commission introduced the revised report and presented its content. The Commission pointed out that the draft should be discussed in a separate point of the agenda because it does not relates to confirmatory information. No additional comments were received. The Commission informed on its intention to take note of the draft at the following meeting of the Plants, Animals, Food and Feed Committee (PAFF) (October 2016).

4. Clothianidin (revised review report)

The Commission introduced the revised report and presented its content. The Commission pointed out that the draft should be discussed in a separate point of the agenda because it does not relate to confirmatory information. No additional comments were received. The Commission informed on its intention to take note of the draft at the following PAFF (October 2016).

5. Imidacloprid (revised review report)

The Commission introduced the revised report and presented its content. The Commission pointed out that the draft should be discussed in a separate point of the agenda because it does not relate to confirmatory information. No additional comments were received. The Commission informed on it intention to take note of the draft at the following PAFF (October 2016).

6. Sulfuryl fluoride

Not discussed.

7. Oxyfluorfen

The Commission informed Member States that the intention was to move forward to restrict the approval of oxyfluorfen for use at a maximum rate of 150 g active substance per hectare per year, to ensure the protection of aquatic organisms.

Final comments were requested. Member States were informed that a Technical Barrier to Trade notification would be required.

8. Tetraconazole

Not discussed

9. Fluquinconazole

Not discussed

10. Metazachlor

Not discussed

11. Prochloraz (revised review report to be noted) - *r emoved from agenda*

12. 1-NAD (revised review report to be noted) - *r emoved from agenda*

13. 1-NAA - *r emoved from agenda*

14. Buprofezin

The Commission informed Member States that the intention was to move forward to restrict the approval of buprofezin to use only on crops that are not subject to industrial processing in order to ensure consumer safety (to prevent exposure to aniline that forms during processing conditions).

Further comments were requested. Member States were informed that a Technical Barrier to Trade notification would be required.

15. Malathion

Not discussed

16. Tri-allate

Not discussed

17. Diclofop

Not discussed

18. Cyflumetofen

Not discussed

19. Napropamide

Not discussed

20. Dicamba (revised review report to be noted)

The Committee presented the review report in which it is clarified that all involved evaluation authorities, including EFSA, agree with the RMS Denmark that the submitted confirmatory information adequately resolve the matter. It is proposed to take note of this amended review report.

21. Fluroxypyr

A short update on how each confirmatory data point has been addressed was given to Member States. The Commission informed that an amendment to the approval was necessary to include a maximum level for one relevant impurity in technical material. For the other points it was not foreseen to have any further EFSA consultation.

A draft revised review report was presented and comments were requested.

22. Tall oil pitch

Member States were provided with a brief summary of the situation following the further evaluation of studies. As the data gaps for which the confirmatory data had been requested were still not addressed, a withdrawal of approval was required (in line with previous decisions in similar cases).

23. Tall oil crude

Member States were provided with a brief summary of the situation following the further evaluation of studies. As the data gaps for which the confirmatory data had been requested were still not addressed, a withdrawal of approval was required (in line with previous decisions in similar cases).

24. Straight chain lepidopteran pheromones

The Committee referred to the recent EFSA technical report on the review of confirmatory studies related to assessment of genotoxicity of aldehyde groups.

It is proposed to consider the open issue as addressed on the basis of a weight of evidence approach. Several Member States' experts considered the battery of tests sufficient to prove the absence of any genotoxic effect on the basis of EFSA Scientific Opinion on genotoxicity testing strategy (2011).

Member States were asked to comment on this approach by 19 August 2016.

25. Methyl nonyl ketone (lack of data submission).

The Commission explained that the applicant has now been given the possibility to submit its comments on the absence of the requested data. In the case of an unsatisfactorily answer a proposal for withdrawal of the substance will be drafted.

26. AOB

None.

A.05 Article 21 Reviews:

- Diflubenzuron

The Commission referred to the information received from Member States about authorisations in non-edible crops, which was made available on CIRCABC. It summarised the recent discussion in the Committee, provided further information on the proposed way forward and explained its reasoning. The Commission asked Member States to send feedback on the proposed approach by 26 August 2016.

A.06 Amendment of the conditions of approval:

1. Abamectin

Comments on the EFSA conclusion were received from a Member State and the Notifier. The Commission will now proceed with drafting the revised review report and the draft regulation to amend the condition of approval, as no critical issues of concern were identified during the peer-review. Some issues may need still to be solved. Member States are invited to provide their comments on the way forward by the 19th August.

2. Fenazaquin

The Commission summarized the "state of play" of the dossier.

Fenazaquin was approved by Directive 2011/39/EU with restrictions that allowed only uses in greenhouses and ornamentals due to major concerns identified in the dossier (risk to consumers and aquatic risks).

The applicant submitted an application according to Article 7 of Regulation (EC) No 1107/2009 asking for some of the conditions of the approval of the active substance to be lifted.

In compliance with Article 12 of Regulation (EC) No 1107/2009, EFSA delivered its Conclusions following the evaluation of the new data submitted.

Following the assessment of the EFSA Conclusion, the Commission was of the opinion that it was not possible to modify the current conditions of approval.

An implementing regulation to "confirm" the conditions of approval was presented for discussion and possible vote in the Standing Committee of December 2014.

However, in 2014 the Commission draft Regulation was not supported by a qualified majority of Member States. The draft was withdrawn from the vote.

The Commission announced that a formal internal consultation was necessary to decide on the way forward.

3. 8-Hydroxyquinoline

Comments on the EFSA conclusions were received from a Member State and the Notifier. Member States were reminded that the active substance approved under Directive 91/414/CEE is considered to be classified as Reprotoxic Category 1B, according to Annex II of Regulation (EC) No 1107/2009. The Commission will now proceed with drafting the revised review report and the draft Regulation to deny the amendment of the condition of approval. Member states are invited to provide their comments on the way forward by the 19th August.

4. Acrinathrin

The Commission repeated its view that, based on the EFSA conclusion, it is not possible to consider a lifting of the existing restrictions in use as it would trigger an unacceptable risk for aquatic organisms. At the same time EFSA indicated that the consumer exposure risk cannot be adequately assessed given the insufficient residue trials at the higher doses. A review report in this sense had already been tabled in March but is now completed with a provisional Regulatory Decision confirming the need to maintain the current restrictions. It will further be explored if such an act is indeed necessary but the Commission believes there is a degree of support from Member States should such act needs to be voted.

However, it has been reported by Member States, and indicated in the Reasoned (MRL) Opinion by EFSA as regards the substance, that the existing restrictions may not be fully applied by some Member States. The Commission urges these Member States to ensure that GAPs, not in conformity with the restrictions (which moreover are now reconfirmed) are withdrawn as soon as possible. This matter will continue to be followed up closely in this Committee.

A.07 Basic substances:

1. Pilot projects: state of play

No new information.

2. New dossiers received

i. Salt

Application considered admissible.

ii. Extension for whey

Admissibility check ongoing.

Point added to original agenda:

iii. Fatty acids C7-C18 and C18 unsaturated potassium salts with CAS number 67701-09-01

Application considered not admissible as this substance is already approved as a regular active substance and authorised to be used as a PPP in several member States.

3. EFSA Technical Reports

i. Talc

The Commission referred to the recent EFSA outcome of the consultation with Member States which underlined a possible concern with respect to inhalation exposure. A decision will be drafted after having allowed comments from applicant.

Following 2 points added to agenda:

ii. Satureja montana L

The Committee received EFSA's technical report and started drafting the draft review report.

iii. Origanum vulgare L.

The Committee received EFSA's technical report and started drafting the draft review report.

4. Draft Review Reports for discussion

i. Sunflower oil

The Commission referred to the uploaded draft review report and comments received from applicant. The report would support the approval of sunflower oil as the basic substance to be used in tomato not for other uses which have not been sufficiently assessed to demonstrate absence of any harmful or unacceptable effect. Member States to comment by 19 August 2016.

ii. Equisetum arvense (revised review report for extension of use)

The Commission referred to the uploaded amended review report which would allow the extension of use of the basic substance on mulch application. MS to comment by 19 August 2016.

Point added to agenda:

iii. Sodium hydrogen carbonate (revised review report for extension of use): application for an extension of use as a herbicide for potted plants in greenhouses.

The Commission considers the proposed extension of use to be covered by the risk assessment made for the original application and in the draft review report proposes to approve the extension. The Commission proposes the same procedure as for Equisetum arvense. Member States were asked to send in their comments on the draft review report before 16 September 2016.

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

1. Draft Guidance Document (GD) 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)

Comments were received from a Member State on the revision of the GD presented to the Standing Committee in May. Input was also received from some stakeholders which led to a new revision, which will be circulated right after the Standing Committee. Member States comments on the new provision regarding data protection are welcomed. The document will be presented for endorsement in October.

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 for discussion only)

No comments were received from Member States on the revision of the GD presented to the Standing Committee in May. Further minor changes were brought in the draft revised document by the Post Annex Inclusion Group which led to a new revision, which will be circulated right after the Standing Committee. The document will be presented for endorsement in October, together with the Guidance Document under Pt. A 08.02.

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

The Committee presented the revised SANTE document, which is based on previous discussions summarised by the United Kingdom and includes the AAOEL derivation though starter as an Annex.

The Committee proposed a transition period of at least 6 months from taking note. This transition period would apply to the new elements of the revised document, for the old elements which are already applied no new transition period is envisaged.

Member States were asked to send in any comments by 19 of August, with the target to take note of the revised document at the next PAFF meeting.

4. Draft Guidance Document on Rules for Revision of Assessment Reports (doc. SANTE/10180/2013 Rev. 2 to be noted)

Comments were received from two Member States on the revision of the GD presented to the Standing Committee in May. These comments need to be addressed by the Post Approval Issues (PAI) Group. So the draft was referred back to this group for clarification and where necessary further amendment.

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

One notification from Germany has been uploaded. It lists amendments of the use conditions for all products containing pendimathalin and/or prosulfocarb which are authorized in Germany.

The Standing Committee took note of the notification from Germany.

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

Eight notifications were uploaded on CIRCABC. Two of them are clearly outside the scope of Article 36(3). For three others, where there are serious doubts, the Commission gives the notifying Member States as well as the reference Member States the opportunity to provide further clarification.

The Committee took note of three notifications, submitted by France and the United Kingdom.

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

Cyantraniliprole (Belgium)
Flocoumafen (Czech Republic)
Abamectin (Denmark)
Azadirachtin A (Denmark)
Carfentrazone-ethyl (Denmark)
Clethodim (Denmark)
Thiacloprid/Deltamethrin (Estonia)
Indoxacarb (Finland)
Clomazone (Germany)
Halosulfuron methyl (Germany)
Spinosad (Germany)
Spirotetramat (Germany)
Acibenzolar-S-methyl (benzothiadiazole) (Greece)
Paraffin oil/(CAS 8042-47-5) (Greece)
Propanil (Greece)
Quinclorac (Greece)
Spinetoram (Greece)
Tau-Fluvalinate (Greece)
Aclonifen (Hungary)
EaH1, EaH2 bacteriophage (Hungary)
Kasugamycin (Hungary)
Penoxsulam (Hungary)
Pyrethrins/Rape seed oil (Hungary)
Triclopyr (Hungary)
Asulam (Ireland)
Fluopyram (Ireland)
Spinosad (Ireland)

1,3-Dichloropropene (Italy)
Cyantraniliprole (Italy)
Spinetoram (Italy)
Terbacil (Italy)
Tricyclazole (Italy)
Pretilachlor (Italy)
Propanil (Italy)
Bacillus thuringiensis subsp. Kurstaki strain ABTS-351 (Lithuania)
Lime sulphur (Calcium polysulphid) (Luxembourg)
1,3-Dichloropropene (Malta)
Abamectin (Norway)
Quinoclamine (Norway)
Fenpyroximate (Poland)
Fosthiazate (Romania)
Metalaxyl-M/Mancozeb (Romania)
Bifenazate (Slovakia)
Copper hydroxide (Slovakia)
Cyprodinil/Fludioxonil (Slovakia)
Emamectin (Slovakia)
Etofenprox (Slovakia)
Flonicamid (Slovakia)
Fluopyram/Trifloxystrobin (Slovakia)
Methoxyfenozide (Slovakia)
Pyrethrins/Rape seed oil (Slovakia)
Spirodiclofen (Slovakia)
Spirotetramat (Slovakia)
Thiram (Slovakia)
8-methyl-2-decanol propanoate (Slovakia)
Alpha-Cypermethrin (Slovenia)
Chlorpyrifos-methyl (Slovenia)
Etephon (Slovenia)
Lime Sulphur (Calcium polysulphide) (Slovenia)
Myclobutanil (Slovenia)
Spinosad (Slovenia)
Spirotetramat (Slovenia)
Chlorpyrifos-methyl (Spain)
Cyantraniliprole (Spain)
Emamectin benzoate (Spain)
Natural seed extract of Camellia sp. (Spain)
Pendimethalin (Spain)
Propanil (Spain)
Pyraclostrobin (Spain)
SCLPs (Spain)
Spinetoram (Spain)
Spinosad (Spain)
Spirotetramat (Spain)
Thiophanate-methyl (Spain)
Quinoclamine (Sweden)
Asulam (United Kingdom)

The Committee took note of the notifications submitted by Belgium, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Malta, Norway, Poland, Romania, Slovakia, Slovenia, Spain, Sweden and 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).

The Commission urged Member States to notify all provisional authorisations granted by the end of July 2016.

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

1. NAP (National Action Plans) Report

No new information.

2. State of play

Following a recent reorganisation in the Directorate General for Health and Food Safety (DG SANTE), the responsibility for the Directive 2009/128/EC has been transferred from 15 July onwards to the Directorate F Health and Food Audits and Analyses Unit F3. Unit E4 is currently working with colleagues to ensure a smooth efficient handover. Next meeting of the experts working group will be organised in cooperation in Bruxelles on 9 November 2016.

Report and presentations of the recent Integrated Pest Management (IPM) demonstration farms workshop held in Bonn are made available in the CIRCABC specific folder.

Finally, the Commission brought the attention of Member States to the coming SPISE workshop on the inspection of pesticides equipment which will be held in Barcelona from 13 to 15 September 2016. Considering also the implementation of related provisions on inspection included in Directive 2009/128/EC should be finalised in November 2016, it is particularly recommended Member States to promote participation to this relevant event.

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

EFSA provided feedback on the recent meeting of the Pesticides Steering Network (PSN), which included a one-day workshop dedicated to improve the peer-review process. The workshop was very effective with several proposals for further improving the peer-review process. EFSA will prepare a preliminary action plan for further discussion and agreement by the PSN and to be presented to the PAFF meeting in early 2017. In addition EFSA reported on the need for a corrigendum of the Plant Protection Products and their Residues (PPR) Guidance Document on aquatic ecotoxicology, regarding some issues identified in the general expert meeting on ecotoxicology held in 2015 and confirmed by the Panel. Member States' experts will be involved in the correction through a dedicated meeting of the PSN. In addition, the report of the general expert meeting on toxicology held in 2016 has been consulted with the Member States and will be published soon. The PSN minutes are currently under consultation with Member States and will be also published after adoption.

The PPR Panel held in June an open plenary meeting in Brussels. As scheduled, the Panel adopted the GD on the residue definition and is currently concluding by written procedure the adoption of the case studies. The guidance document will be published by EFSA and presented at the next PAFF meeting. The Panel also endorsed for public consultation the Scientific Opinion on the potential link of pesticides exposure with Parkinson disease and childhood leukaemia, using the Adverse Outcome Pathway approach; this is part of the EFSA activities for improving the use of epidemiological studies in the risk assessment of pesticides, which will include a Scientific Conference to be held in 2017.

EFSA also informed that the methodology for herbicides assessment under Article 4(7) has been finalised and a Technical Report will be published soon. Member States were pre-notified and some editorial corrections may be done following comments received.

Regarding the EFSA MATRIX project on dossiers and electronic submissions EFSA reported that, following the discussions held in the EU preparatory meeting for the OECD WGP, EFSA will be involved in the pilot for the new dossier preparation/submission system for the new xml format of the pesticides dossiers (GHSTS) on behalf of the Commission.

EFSA reported on the outcome of the expert meeting for assessing the confirmatory data regarding the risk assessment of neonicotinoids to bees, and indicated that due to the large number of studies, and the additional work required for assessing the

confirmatory data, the EFSA conclusions under Article 21 would require an extension of the deadline.

Finally, EFSA informed that the joint document with European Chemicals Agency (ECHA) regarding the divergent opinion on the classification of flutianil is under preparation and, that following a request from ECPA regarding the genotoxicity assessment of several active substances, EFSA requested a clarification from the applicants on the claims for each specific substance. EFSA has considered the received claims but has concluded that the EFSA Conclusions reflect in all the cases a proper reflection of the current scientific knowledge according to the expert discussion at the toxicology peer-review meetings, and therefore there is no need for modifying the conclusions.

A.15 News from Health and Food Audits and Analysis Directorate (former Food and Veterinary office (FVO).

In cooperation with the Health and Food Audits and Analysis Directorate, Unit E4 co-organised the next workshop concerning Article 68 reporting template which will be held in Brussels on 21 and 22 September and the follow up workshop concerning Formulation laboratories to be held on 22 and 23 September 2016.

A.16 Report from working groups:

1. Plant Protection Products Application Management System (PPPAMS)

A presentation was given by the Commission on the progress of using PPPAMS to handle emergency applications. Member States were also given a general update on ongoing work with PPPAMS and with the data collection exercise.

Member States were asked to continue to use PPPAMS to handle emergency authorisations. The Commission explained that support was available to assist with any problems.

2. Article 68 Enforcement Working group

The Commission informed Member States that a follow up on the workshop held in April 2016 on enforcement matters will be held in Brussels on 21 and 22 September 2016. It will have as the main points of the agenda: exchange on best practices, finalisation of report template, identification of needs with respect to EU Guidance.

3. Post Approvals Issues group (PAI)

The Commission informed Member States about the latest discussions that occurred in the PAI Group. Most of them were addressed under specific points during the meeting. However, the Commission presented the discussion launched in order to update the remit of this working group, in order to improve further the high quality outputs and the exchange of information between the Standing Committee and the Zonal Steering Committees. Member States wishing to provide their input to the discussion could send their comments before the 19th August.

4. Unacceptable co-formulants

The Commission informed Member States about the latest developments related to co-formulants. Experts started to discuss on how to assess the risk of candidate unacceptable co-formulants notified by Member States. Member States were asked their view about the guidance to be drafted on unacceptable co-formulants. Their feedback is requested by the 19th August.

5. Biopesticides

The Commission informed Member States about the discussions on-going in the Working Group (WG) on Biopesticides. The revised Draft Assessment Report (DAR) template for micro-organisms is also finalised. It will be implemented in time for the renewal of micro-organisms under the 4th program of renewal. The WG will be reconvened to discuss the outcome of the Dutch Workshop held on 15 November 2016 on Micro-organism Toxicology. They will also discuss the issue of products containing killed micro-organisms.

6. Seed treatment

The Commission informed about the last development in drafting the guidance document on seed treatment. Some inputs are still lacking as new data was made available recently. Finalisation of the document is expected during fall 2016.

7. Sustainable plant protection experts group Dutch proposal

The expert's group implementation plan was endorsed by the AGRIFISH Council in June. The expert group will continue its work to support the implementation of the plan and to report on progress to the PAFF Committee and the Council. Next meeting is planned on 3 October. The Commission asked Member States that do not yet participate in the expert group to consider nominating an expert.

8. DRAW Setac-Workshops

The Commission informed about a new series of SETAC workshops initiated in February 2016 which focus on drift exposure. A second workshop is planned for February 2017. The Commission is exploring if supporting participation of Member States is possible.

A.17 OECD

The Chair of the OECD Biopesticides Steering Group reported on the Seminar on Microbial Sensitisation and the BPSG meeting which were held in Paris in June.

The Commission reported the main outcomes of the June meeting of the OECD Working Group on Pesticides. Facing a dramatic drop down of resources and funding, the WGP and the OECD Secretariat performed a review of the existing Expert Groups in order to rationalise the work done within their remit.

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. Commission Communications amending Commission Communications (2013/C 95/01-95/02) as regards the effects on bees

The internal consultation on the two communications started. A draft will be available to Member States for comments. The plan is to have it adopted at the same time of the BEE GD and Uniform principles. However no vote is needed.

4. AOB

None

A.19 Court Cases

No news.

A.20 Endocrine disruptors.

The Commission updated that as a follow up to the ad-hoc PAFF meeting the 22 of June, so far a total of 6 Member States sent contributions regarding the draft criteria to identify endocrine disruptors (published 15 June 2016). Member States were invited to send further comments by the 19 of August, in order to be able to organise a further PAFF meeting on the topic early after the summer break (the 21st of September was mentioned as a potential date).

Furthermore, the Commission informed about the meeting with stakeholders to present the draft criteria (Ad-hoc Working Group meeting of the Advisory Group on the Food Chain, Animal and Plant Health on criteria to identify endocrine disruptors), which took place on 30 June 2016. The minutes of the meeting are available via the DG SANTE website.

The Commission informed also that the consultation of third countries via TBT and Sanitary and Phytosanitary Systems (SPS) notification is in progress, as well as the consultation of the general public of the draft legal act on the criteria via the feedback mechanism in the context of the Better Regulation framework.

Further, the Commission explained that it is of interest to be able to apply the new criteria, once adopted, without delay. In order to be able to do so letters to both the

European Food Safety Authority and the European Chemical Agency were sent and discussion with the agencies have been initiated.

Finally, the Commission mentioned the publication of the screening study report, which is available via the DG SANTE website.

A.21 Minor Uses:

- State of play

A presentation was given by the EU Minor Uses Coordination Facility (EUMUCF) to update the members of the Standing Committee.

As the first grant agreement ended on 14 April 2016, the EU Minor Uses Coordination Facility (EUMUCF) has prepared a Final Narrative Report and Final Financial Report covering the first year, which is now scrutinised by the Commission. 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. As 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 for how other Member States can contribute, is in preparation and should be available by the end of 2016.

It is envisaged that the EUMUCF will be fully staffed - including a Technical Expert - by the end of the third quarter of 2016.

The EU Minor Uses Database (EUMUDA) is in the process of being updated. As it is foreseen that a minor uses project will eventually result in an application for an extension of a minor uses authorisation, the structure of EUMUDA will as far as possible, be aligned to the PPPAMS structure.

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

Member States highlighted that according to Regulation (EC) No 1107/2009 no efficacy data are necessary to grant extensions for minor uses authorisations.

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

i. CO2

It is considered that the addition of small doses of CO2 to the atmosphere in protected crops to increase the yields is not covered by the PPP legislation. Indeed, this activity is assimilated to nutrients, which are explicitly excluded by Article 2(1)(b). The Scope document will be amended accordingly.

2. Questions and answers

No new questions and 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 informed Member States about a letter, co-signed by DG GROW, DG ENVI and DG SANTE, to urge Member States to submit application dossiers regarding classification and labelling for pesticidal active substances to the ECHA. This letter will be sent in the coming weeks to the permanent representative of each Member State.

A.24 Glyphosate:

- State of the dossier

Regarding the note-taking at the Committee meeting on 10/11 December 2015 of revised toxicological reference values (ADI, ARfD, AOEL) as proposed in the EFSA Conclusion, several Member States confirmed their view that the review of the existing MRLs under Article 12 of Regulation (EC) No 396/2005 should be carried out applying those revised reference values, even though the approval of glyphosate has not been renewed but the existing approval extended.

A.25 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.26 European Crop Protection Association (ECPA) letter on genotoxicity assessments for active substances.

Point added to the agenda.

Member States were made aware of the letter send by ECPA on the issue of genotoxicity assessments following this issue being raised for a number of substances in EFSA Conclusions. The Commission is considering the letter.

A.27 Tefluthrin - Article 56 submission by Syngenta (Germany).

The new studies were submitted concerning tefluthrin in the framework of article 56 to the rapporteur Member State Germany. Germany concluded that the new studies formally result in a new aquatic endpoint, but as they do not alter the outcome of the risk assessment, no addendum to the draft assessment report is necessary. The one still unresolved issue (dust deposition) shall be addressed in the seed treatment guidance document which is currently under preparation.

The Commission and a number of Member States agree to this proposal. However, some Member States request a more formal approach concerning potential amendments of the list of endpoints in the draft assessment report and the EFSA conclusion.

The post approvals issues expert group will be approached to discuss the issue further with Member States and EFSA.

A.28 Phosphonic acid (inorganic metabolite) - assessment of relevance (Germany)

There is no new information concerning this question asked by Germany. The Commission will come back on this point at the meeting in October.

A.29 Question from Denmark and Post Approval Issues (PAI) regarding the implementation of Acute Acceptable Operator Exposure Level (AAOEL).

See point A 08.03.

A.30 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)

Point removed from agenda.

A.31 Dimethoate: notifications by France according to Article 21 and 71 of Regulation (EU) 1107/2009.

Point removed from the agenda.

A.32 European Crop Protection Association (ECPA) letter on protection goals (NTP).

The Commission provided this letter for information. The Commission reiterated the intention to work on setting specific protection goals with risk managers of Member States. More detailed planning is expected for the fourth quarter of 2016.

A.33 Acrinathrin – implementation of approval restrictions.

Item covered under sub point A 06.04.

A.34 AOB

1. Status of variants – case of 2,4-D.

The Commission has been made aware that in the PAI group it was questioned whether 2,4-D EHE (the ethylhexyl ester) is still covered after renewal of the substance while the evaluation dossier focussed on 2,4-D (acid) only.

The Commission acknowledges that in the first inclusion in 2001 both the ester and the acid had been assessed (note they had been supported by different notifiers) and both their endpoints figured in the review report at that time.

The Commission will explore this matter in depth but, at first sight, the use of the common (ISO) name of a substance in the regulation does not per se legally preclude that its simple variants (such as salts or esters) are used in the formulated products. It is recalled that products containing 2,4-D DMA (the dimethylamine ester) had been commercialised after 2001 while that ester did not figure at all in the original review report.

However, that does not mean such variants would escape from any form of assessment and, in line with existing guidance, their assessment was part of the re-registration process and performed at MS level. It will now be further explored in PAI and PAFF whether the new Regulation (EC) No 1107/2009 would necessitate an update of the pertinent guidance document reflecting the former practice.

B.01 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)

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

One Member State vote against because of the leaching of metabolites to groundwater. Three Member States abstained due to leaching of metabolites to groundwater. One Member State abstained as no confirmatory data requirement was set for toxicological data for the ground water metabolite IN-M2G98.

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 isofetamid, 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/10401/2016 Rev. 1)

The Commission introduced the draft and presented its contents. Member States expressed their positions on the draft. One Member State voted against as the technical specification is based on a pilot plant production and thus not finalised.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of the active substance B*acillus amyloliquefaciens* strain MBI 600, 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/10008/2016 Rev. 2)

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

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.

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

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).

The Commission introduced the draft and presented its contents.

The Commission welcomed the numerous comments received from Member States including in some cases, those arriving very late. The Commission informed that after

attentive analysis of the comments, it plans to modify the current draft with the aim to take into account the comments received. As soon as the new draft will be available, it will be sent to Member States for a second and last round of comments. The Commission informed that at this stage they do not see the need of an additional expert meeting

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 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 Commission introduced the draft and presented its contents. Member States expressed their positions on the draft. The draft act was supported by a qualified majority of Member States.

Four Member States voted against for different reasons, two for the risk for aquatic organisms and two for potential compliance with interim ED criteria. Two Member States abstained one for risk to aquatic organisms, and one for possible ground water leaching metabolites.

Vote taken: Favourable opinion.

B.07 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.

One Member State stood against and another one abstained as they considered the risk to non-target plants, aquatic organisms were not acceptable or sufficiently addressed.

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 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)

There was no discussion as the inter-Service consultation is still ongoing.

Vote postponed

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance ethofumesate 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/10120/2016 Rev. 2)

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

Vote taken: Favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, as regards the criteria for the approval of low risk active substances.

The Commission informed this act the CIS is not yet ready. In addition, the Commission has introduced a new procedure to increase transparency and allow the general public to know and comment on specific legislative proposals of wider relevance. The so called feedback mechanism implies one month of public consultation and consideration of comments received before being able to proceed with the vote. More extended information is available at the following address: http://ec.europa.eu/info/law/contribute-law-making_en

Vote postponed

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate (Draft Review Report doc. 6511/VI/99 and Addendum SANTE/11051/2016 Rev. 0).

The Commission introduced the draft and presented its contents. It referred to feedback received from applicants following their consultation in the context of the Article 21 review procedure. All feedback was made available on CIRCABC ahead of the meeting.

Member States expressed their positions on the draft.

Vote taken: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of the active substance tricyclazole, 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/11866/2015 Rev. 0).

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

Three Member States voted against and three Member States abstained. The reasons had already been provided by Member States both in writing and verbally in previous meetings; several Member States considered that although the data package was deficient and incomplete that the substance could be approved with confirmatory requirements. One Member State considered that the concerns were not sufficient to prevent the setting of reference values and that approval could be supported. Several Member States expressed their concerns at the lack of solutions for control of rice blast and were concerned about the impact of non-approval on MRLs and the inability to grant emergency authorisations. The Commission explained that despite looking into all possible options and considering the file in detail, a non-approval decision was the only possible option given the concerns identified in the peer review and EFSA Conclusion, which was the third such opinion in which these concerns had been raised.

Member States were informed that the matter would be referred to the Appeal Committee in accordance with the relevant procedure.

Vote taken: No opinion.

M.01 AOB

None.

M.02 Date of the next meeting.

The date of the next meeting was confirmed as 6-7 October 2016.

M.03 New Scientific publications and information submitted by stakeholders.

None.