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 07 MARCH 2016 - 08 MARCH 2016

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/5280b881-6adc-408c-a3d1-143b73319c77*

A.01 Summary Report of previous meetings.

The Member States were informed that the submission of the report from the January meeting is delayed, but the Commission will proceed as quickly as possible.

A.02 New active substances:

1. New admissible dossiers (to be noted)

   i. 1,3-*Dichloropropene*

The Committee took note of the declaration of admissibility provided by the Rapporteur Member State (RMS).

2. European Food Safety Authority (EFSA) conclusions

There were no new conclusions to be discussed.

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

i. *Beta-Cypermethrin*

A draft review report and Regulation for approval was presented to Member States. No detailed discussion, but Member States were invited to comment in writing.

One Member State indicated to vote against approval because of the risk to aquatic organisms and requests further clarification about the ratio of isomers.

ii. *Beauveria bassiana* strain 147

A draft review report and Regulation for approval was presented to Member States. No detailed discussion, but Member States were invited to comment in writing.

iii. *Beauveria bassiana* strain NPP111B005

A draft review report and Regulation for approval was presented to Member States. No detailed discussion, but Member States were invited to comment in writing.

iv. *Reynoutria sacchalinensis* extract

The proposal was explained to the Member States. Three Member States and the applicant have sent comments since the last meeting. Member States were invited to comment in writing by 23 March 2016.

v. *Saccharomyces cerevisiae* strain LAS02

The Commission seeks to approve this micro-organism as a low-risk substance. Comments were received from the notifier and Member States. They were taken into account in revised versions of the draft Regulation and review report. The Commission confirmed that this microbial strain of S. cerevisiae resistant to one antibiotic used in human medicine could be approved as a low-risk substance. It is considered that this was not a significant concern for S. cerevisiae. A vote is foreseen in May.

vi. *Cyantraniliprole*

One Member State sent in comments since the last meeting. Formal positions of Member States were requested by 15 April 2015.

vii. *Isofetamid*

A draft review report and Regulation for approval was presented to Member States. No detailed discussion, but Member States were invited to comment in writing by 15 April 2016.

viii. *Bacillus amyloliquefaciens* strain MBI 600

A draft review report and Regulation for approval was presented to Member States. No detailed discussion, but Member States are invited to comment in writing by 15 April 2016.

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)

Agenda point for information only; no discussion.

2. List of studies relied upon for Annex I Renewal Projects (AIR) assessments

No news under this point.

3 AIR II: State of play

Decision-making for some of the substances under AIR II is close to finalisation and it is likely that decisions can be taken in time, before 30 June. For the remaining substances, an extension of the approval period will be presented for a vote under another agenda point.

4 AIR III: State of play

The Commission is concerned about the overall slow progress in the AIR III programme. For several substances expiring in 2016 no EFSA conclusion is available, and it will not be possible to finalise the decision-making process in time. It will therefore become necessary to extend the approval period for these substances, which will necessarily negatively impact on the deadlines for AIR III substances expiring in 2017.

5 AIR IV: State of play

Further to the plans for prioritizing the substances of the AIR IV programme according to their potential risk, the Commission currently prepares a Decision which will be presented to the Standing Committee in May.

6 European Food Safety Authority (EFSA) conclusions:

i Thifensulfuron

The Commission recalled the intention to proceed with a proposal of renewal following up on the conclusions of EFSA, was already substantiated in the meeting of January. The Commission brought attention to the draft review report which has been submitted to the applicants and uploaded in CIRCABC for the Plants, Animals, Food and Feed Committee (PAFF). The delegates will find also comments received from the applicants and Sweden's position. Commission asked Member States to comment by 1 April 2016 to be able to proceed with the legislative proposal.

ii Fenamidone

For information; no discussion on the subject.

7 Draft Review Reports for discussion:

i. Thiabendazole

A revised review report was presented to the Member States. A Member State asked to clarify further why some uses were not retained in the Review Report. Member States were invited to comment in writing by 1 April 2015.

ii. Amitrole

The Commission presented a draft Regulation concerning the non-renewal of approval of the substance. Formal positions of Member States were requested by 30 March. A vote is foreseen for April; Member States will be informed about the date in time.

iii. Cyhalofop-butyl

A revised review report was presented to the Member States. No detailed discussion, but Member States were invited to comment in writing by 1 April 2015.

iv. Triasulfuron

The Commission presented the non-renewal of the substance. Due to remaining uncertainties on the genotoxicity of the parent and of certain impurities, EFSA did not set the reference toxicological values and could not finalise the human exposure assessment. New comments by the notifier have been tabled and carefully examined. However, the alternative of the setting of these values by the risk managers themselves, based on the Draft Assessment Report (DAR), was not firmly supported. Due to the ongoing Technical Barriers to Trade (TBT) procedure, it is not possible to vote now and therefore the dossier will be brought to another section of this Committee at a later stage. Formal positions of Member States were requested by 30 March. A vote is foreseen for April; Member States will be informed about the date in time.

v. Bentazone

Comments were received from some Member States. A revised review report was presented. No detailed discussion, but Member States were invited to comment in writing by 1 April 2015.

vi. Isoproturon

The Commission presented a draft Regulation concerning the non-renewal of approval of the substance. Formal positions of Member States are requested by 30 March. A vote is foreseen for April; Member States will be informed about the date in time.

vii Famoxadone

Comments were received from some Member States. The Commission proposal was further explained. Member States were invited to comment in writing by 1 April 2015.

viii. Diquat

A draft review report was presented to Member States. No detailed discussion, but Member States were invited to comment in writing by 15 April 2015

ix Picolinafen

The Commission proposes to renew the approval of picolinafen without restrictions or confirmatory information. Comments were received from some Member States. A revised review report was presented, addressing the concerns raised on impurities in the technical active substance, risk to wild herbivorous mammals and potential risk to non-target plants. A vote is foreseen in May.

x. Ethofumesate (AIR3)

Ethofumesate is the first substance of AIR III for which a conclusion was issued by EFSA. A draft review report and Regulation were presented and Member States were invited to send in comments in writing.

Point added to original agenda:

xi Metalaxyl-M

Formal positions requested from Member States by 1 April 2016.

A.04 Confirmatory data:

1. Epoxiconazole

While most of the requests for confirmatory information have been satisfactorily addressed, there are still two remaining issues that need consideration. As regards the need or not to include metabolite 480M06 in the residue definition, the review report suggests this should be done at the renewal stage. As regards the long term risk to herbivorous birds and mammals which is borderline but highly dependent of local situations, it is proposed that the subject is further assessed at national level, when authorisations are sought. It would seem that Member States are generally in agreement with the approach taken. As regards the non-applicability of the approval criteria of Regulation (EC) No 1107/2009 to confirmatory information requested under Directive 91/414/EC, the Commission is willing to cast in writing its legal analysis should this be helpful to the Member States. It is intended to request the Committee to take note of the revised review report at the meeting in May 2016

2. Bifenthrin

The Commission proposes that the discussion focusses on the issue at stake, namely the potential for recovery of non-target arthropods (NTA) in-field. Member States have been requested to examine whether safe uses, based on the Uniform Principles, have been demonstrated with the (normal) rate of 10g/ha. Germany is currently doing the evaluation; however it did not conclude on this matter. In response, it made some comments as regards bioaccumulation. The Commission explained that this discussion is a bit premature but will be dealt with in the coming months, when the review of the bioaccumulation/biomagnification monitoring will be finalised

3. Dodine

The Commission updated the experts on the "state" of play of the dossier. The confirmatory data were submitted within the deadline. The assessment has been carried out in line with the Guidance Document (GD) on the procedures for submission and assessment of confirmatory data. The Commission requested EFSA to organise a peer review of the RMS evaluation of the confirmatory data submitted in relation to ecotoxicology. EFSA delivered its conclusions on 20 August 2015. The Commission proposes that, on the basis of the outcome, the conclusions of the original risk assessment are not modified by the evaluation of the submitted confirmatory data. A revised review report is available for Member States comments. It is intended to request the Committee to take note of the revised review report at the meeting in May 2016.

4. Thiamethoxam

The confirmatory data were requested following the restriction on uses laid down in Commission Implementing Regulation (EU) No 485/2013. The assessment has been carried out by the RMS (Spain). From this assessment it appears clear that very few data were submitted by the applicant. EFSA is currently working on the finalisation of the technical report. It is intended to inform the Committee on the Commission position on this file at the meeting in May 2016.

5. Sulfuryl fluoride

This dossier was extensively presented at the last PAFF Committee meeting in January. In line with the provisions of the regulation for biocide uses, a request for atmospheric monitoring is set. As residue data are lacking, Commission sees a need to restrict the approval to forbid the fumigated foodstuff and feedstuff to enter the market. Feedback was received from Member States. An amended review report has been presented, addressing the concerns on MRL compliance of the treated foodstuffs.

6. Bromuconazole (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.

7. Oxyfluorfen

Several Member States submitted comments following the discussion in January, which were presented to the Committee.

8. Tetraconazole

Requested clarification by the RMS Italy is available and will be submitted to the Commission in writing so that progress can be made on this dossier.

9. Fluquinconazole

No discussion as the EFSA conclusion on some outstanding ecotoxicological questions is only due by 30 March

10. Metazachlor

A revised addendum, including further clarification from the applicant, has been circulated by the RMS United Kingdom for comments. These clarifications do not change the RMS' initial position that acceptable scenarios for groundwater exist. The dossier will be debated again once the technical report by EFSA will be finalised.

11. Prochloraz

The Commission is of the opinion that technically the report is in a final stage and that note-taking is possible at the meeting in May 2016. It notes already that at least one Member State may refrain from taking note for more general reasons, linked with the approval as such of the substance.

12. 1-NAD

There seems to be a general consensus as regards the proposal made in the review report as regards the chronic risk to birds. It seems that this report can be noted in the meeting in May 2016.

13. 1-NAA

There seems to be a general consensus as regards the proposal made in the review report as regards the chronic risk to birds. It seems that this report can be noted in the meeting in May 2016.

14. Buprofezin

The Commission outlines a draft amended review report. No detailed discussion

15. Pyridaben

The Commission updated the Committee on the state of play of the dossier. The confirmatory data were submitted within the deadline. The assessment has been carried out in line with the Guidance Document on the procedures for submission and assessment of confirmatory data. The Commission requested EFSA to organise a peer review of the RMS evaluation of the confirmatory data submitted in relation to ecotoxicology. EFSA delivered its conclusions on 14 January 2016. The Commission proposes that, on the basis of the outcome, the conclusions of the original risk assessment are not modified by the evaluation of the submitted confirmatory data. A revised review report is available for Member States comments. It is intended to request the Committee to take note of the revised review report at the meeting in May 2016.

The following 4 points were added to the original agenda:

16. Malathion

The Commission outlined the confirmatory data submitted by the applicant and the position of the rapporteur Member State. No detailed discussion.

17. Tri-allate

The Commission outlined the confirmatory data submitted by the applicant and the position of the rapporteur Member State. No detailed discussion.

18. Diclofop

The Commission outlined the confirmatory data submitted by the applicant and the position of the rapporteur Member State. No detailed discussion.

19. Cyflumetofen

Cyflumetofen was approved in 2013 as an acaricide, with a pending request of three pieces of confirmatory data. The concerns raised were related to the presence of a groundwater metabolite (B3) with potential genotoxicity on one hand and on the other hand the risk to aquatic organisms, where a potential endocrine disrupting mode of action could not be ruled out. The Netherlands, as Rapporteur Member State, assessed the confirmatory information and EFSA collated the views of Member States during a commenting round. The technical report states that a peer-review should be organised covering all points. The Commission will draft it shortly in order to keep pace with this set of confirmatory data.

20. AOB

No other points.

A.05 Article 21 Reviews:

1. Diflubenzuron

The Commission informed the Committee about a joint statement from EFSA and the European Medicines Agency (EMA). The two agencies consider that fundamentally there is no divergent scientific view between them. Both agencies agree that the metabolite 4-chloroaniline is genotoxic and carcinogenic.

The Commission summarised the feedback received from Member States so far. It proposed a possible way forward and explained its reasoning. In this context, it asked Member States to inform the Commission about authorisations in non-edible crops by 15 April 2016.

EFSA provided a brief update on the state of play in the court case T-725/15.

2. Chlorpyrifos – state of the dossier

Substance currently under renewal assessment.

A.06 Amendment of the conditions of approval.

No issues to discuss.

A.07 Basic substances::

1. Pilot projects: state of play

The Commission informed of its intention to organise a second meeting of experts group in the second half of 2016.

2. New dossiers received

No new dossiers received.

3. EFSA Technical Reports

No new technical Reports received.

4. Draft Review Reports for discussion

No new draft Review Reports available.

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

1. Draft Technical Guidance Document on the interpretation of points 3.6.3 to 3.6.5 of Annex II of Regulation (EC) No 1107/2009), in particular regarding the assessment of negligible exposure to an active substance in a plant protection product under realistic conditions of use (SANCO/12096/2014) (update)

No progress was made since the last discussion.

2. Draft Guidance Document on Semiochemical active substances used in Plant Protection Products (SANTE/12815/2014 Rev. 4.6, to be noted)

The document (Rev. 4) was presented extensively during the last meeting. Comments were received which led to Rev. 5.1. However, an issue about impurity in the technical active substance was picked up too late to keep the document for noting. The Commission would like to postpone the note-taking to the next PAFF Committee meeting in May. The implementation date would then be 1st January 2017.

3. Guidance Document for applicants on preparing dossiers for the approval or renewal of approval of a micro-organism including viruses according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/12545/2014 Rev. 2, to be noted)

The document was presented during the last meeting and concerns were raised regarding the numbering system provided in the Guidance Document. Further clarification was brought by the Working Group on Biopesticides, which explicitly decided to go for a numbering system of the content of the dossier according to the EU legal requirements and to diverge from the OECD system. The document was noted. The Annex I Renewal project 2nd phase AIR4 program is coming shortly with the notification deadline for the 30th April. This GD applies to the supplementary dossiers which are expected by 30th October 2016.

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

44 notifications were uploaded by the United Kingdom. All of them concern chlorpyrifos.

The United Kingdom wonders whether other member States also need to adapt their authorisations, following the recent change in endpoints. Several Member States confirm that amendments and respective notifications are currently being prepared.

The Committee took note of the notifications sent by the United Kingdom.

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

Notifications were uploaded by Germany (1), Sweden (1) and the United Kingdom (2).

The Commission is concerned about some of these notifications, as Member States seem to refuse mutual recognition for other reasons than those laid down in Article 36(3). The Commission exceptionally accepts referring the four submitted notifications to note taking, but explicitly reserves its position on their content and will follow the issue up with Member States more thoroughly in the future.

The Committee took note of the notifications uploaded by Germany, Sweden and the United Kingdom.

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

Lime sulphur (Belgium)
Trichoderma atroviride strain SC1 (Belgium)
Thiamethoxam (Bulgaria)
Imidacloprid (Bulgaria)
Clothianidin/Beta-Cyfluthrin (Estonia)
Fipronil (Estonia)
Thiamethoxam/Metalaxyl-M/Fludioxonil (Estonia)
Clothianidin/Beta-Cyfluthrin (Finland)
Thiamethoxam/Metalaxyl-M/Fludioxonil (Finland)
Chloropicrin (Hungary)
Clothianidin (Hungary)

Flufenzin (Hungary)
Imidacloprid (Hungary)
Thiamethoxam (Hungary)
Ioxynil (Latvia)
Sodium Silver thiosulphate (Latvia)
Alpha-Cypermethrin (Portugal)
Clothianidin (Portugal)
Propiconazole (Portugal)
Spinetoram (Portugal)
Thiacloprid (Portugal)
Acetamiprid (Portugal)
Ethoxyquin (Portugal)
Imazamox (Portugal)
Clothianidin (Romania)
Imidacloprid (Romania)
Thiamethoxam (Romania)
Chlorpyrifos (Slovakia)
Metalaxyl-M/Fludioxonil (Slovakia)
Tefluthrin (Slovakia)
Pyriproxyfen (Slovenia)
Dazomet (Spain)
Deltamethrin (Spain)
Thiamethoxam (Spain)
(E,Z)-7,9-Dodecadien-1-yl acetate / (E,E)-7,9-Dodecadien-1-yl acetate (Spain)
Metrafenone (Spain)

The Committee took note of the notifications submitted by Belgium, Bulgaria, Estonia, Finland, Hungary, Latvia, Portugal, Romania, Slovakia, Slovenia and Spain.

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.

In particular with a view to notifications for the active substances clothianidin, imidacloprid and thiamethoxam, Member States were urged by the Commission to thoroughly check whether the conditions of Article 53 are fulfilled before granting an authorisation.

A.12 Sustainable Use Directive (SUD) (Directive 2009/128/EC):

1. NAP (National Action Plans) Report

The Commission aims to submit the report to European Parliament and Council during the Dutch Presidency depending on progress in internal consultation.

2. State of play

An Integrated Pest Management (IPM) demonstration farms workshop is planned for the 24 and 25 May. The Commission explores the possibility to provide funding support.

The Commission received a request for opinion from Italy with respect to a proposed mutual recognition of training certificate under Article 5 of SUD in compliance with sectorial Directive which will be made available soon to the SUD delegates.

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

EFSA informed on planned activities of the Pesticides Steering Network (PSN), including a physical meeting on the methodology to be used for assessments under Article 4(7) in March and a discussion at the regular PSN meeting in June on options for improving the peer-review process and involvement of Member States' experts.

EFSA also informed on the on-going public consultation on the PPR Guidance on the Residue Definition, running until 2nd May 2016. EFSA reiterated the key role of Member States in this process, asking Member States to look at the proposals and to submit comments for the consideration of the PPR Panel, and announced that, according to the new mandate and Terms of Reference of the PSN, a dedicated consultation with Member States risk assessors was under discussion by the PSN.

Regarding the alignment of the DAR and Harmonised Classification and Labelling (CLH) report templates, the comments submitted by the different parties have been compiled and EFSA is organising a consultation with the PSN expert group.

In the area of the EFSA peer review of active substances, the Technical Report on the general Expert Meeting on Toxicology is under preparation. Also in the toxicology area, the experts have discussed the best approach for dealing with the setting of the acute acceptable operator exposure level (AOEL). Following the previous discussion, EFSA proposed to establish the acute AOEL based on a case by case assessment for all substances. EFSA considers that the scientific knowledge is sufficient for setting acute AOELs, as well as for concluding that they are not needed, at the peer review expert meetings, and do not recommend tiered approaches based on the need for

refinement for assessing the representative uses. As toxicological reference values are essential for Member States' assessments after approval, EFSA consider that the need for an acute AOEL and the selection of the relevant value should be set at EU level. Consequently, EFSA will request all RMS to assess the need for acute AOEL and to include a proposal that will be discussed at the peer-review expert meeting on toxicology.

The Commission thanked EFSA. Regarding the approach suggested by EFSA concerning the AAOEL, the Commission is concerned about possible conflicts with existing Guidance Documents and asked Member States to provide a position regarding the EFSA proposal. The issue will be put on the agenda of the meeting in May.

A.14 Report from working groups:

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

The Commission gave a brief update on the progress since last meeting. The integration of existing data from Member States databases is progressing. On the part of developments the Commission decided to focus on the module for notifications under Article 53. It can be expected, that the module is ready for uploading information soon. For applications for authorisation arriving at Member State level as from 1 June, the PPPAMS shall be used.

Member States were invited to test the system and to raise any question at the meeting in May.

2. Low risk : working document for proposal to review criteria

The Commission informed on the ongoing work to finalise a reporting table with all comments received which will be sent to expert group. The Commission will now proceed with preparing a draft Regulation to amend Annex II of Regulation (EC) No 1107/2009.

3. Expert group on Article 43

The Working Group on Article 43 was held in November 2015 and the minutes discussed since then. The Commission asked for feedback from Member States at the last PAFF Committee meeting. Comments were received from Belgium, Netherlands, Germany, Sweden. Most of them were taken into account in the revised Q&A document. Member States can find it on the relevant folder on CIRCABC. The Commission has already started the update of the Rev. 13 of the guidance document noted in July 2015. It will be further discussed within the Post Approvals Issues group (PAI) Group during its meeting in March.

4. Post Approvals Issues group (PAI)

There was no meeting of the group since the PAFF Committee meeting in January.

5. Non-acceptable coformulants

The WG held its first meeting in February, with the fruitful participation of 9 Member States, Norway and EFSA, from different fields: risk assessment vs. risk management, toxicology, physics and chemistry. A thought starter was drafted by the Commission. The proposed procedure is a step-wise procedure, each step triggered by the hazard classification of the co-formulant. The goal is to adopt quickly a first list of co-formulants of critical hazard concern. This list will be updated on a regular basis. Questions were raised regarding the approach with hazard-based triggers or the impact on industries, assessment workload or management of products already on the market. Further steps will focus on drafting a risk assessment procedure to identify non-acceptable co-formulants.

The PAFF Committee will be regularly informed as Commission will keep the point on co-formulants as a standing point on the agenda of the next PAFF Committee meeting.

6. Biopesticides

A workshop of the WG on Biopesticides was held on the 18th and 19th February, with supplementary experts coming from the RMS and co-RMS for AIR4 micro-organism active substances. Experts from EFSA, Member States and applicants discussed the content and template for AIR4 dossiers, to be notified by the end of April and submitted before the 30th October. Clarifications and advice to meet the assessors' expectations were summarised in the minutes of the Workshop as bullet points. This document has been uploaded in the folder for this Committee on CIRCABC.

7. Sustainable plant protection experts group Dutch proposal

The Commission informed the Member States on the state of play of the Expert Group on Sustainable Plant Protection. This group is identifying short term and long term actions to increase the availability of low-risk plant protection products and accelerate the implementation of Integrated Pest Management (IPM) in Member States. The group has a monthly meeting schedule. In their February meeting, the group finalised their mandate and discussed a first set of possible actions that could be included in the implementation plan the group is working on. This plan is to be presented in the Agriculture and Fish Council (AGRIFISH) Council in June. Four subgroups of several Member States have been formed to elaborate on specific topics. The next meeting will take place on 21 March 2016.

A.15 OECD

No news.

A.16 Bees:

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

The EFSA assessment of the data collected is ongoing. No discussion at this meeting.

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

Member States are asked to provide the GAPs currently authorised by 1 April 2016.

3. EFSA Guidance Document on the risk assessment of plant protection products on bees and implementation plan (SANCO/10606/2014) "state of play".

Directorate General for Health and Food Safety (DG SANTE) informed that it had received the greenlight to launch the inter-service consultation on this file. It is foreseen to produce a Commission Notice and to use as a legal basis Article 77 of Regulation (EC) No 1107/2009. A draft proposal is not yet available. It is expected to have a draft available at the meeting in May 2016.

4. Uniform principles – Amendment to the Regulation (EU) No 546/2011 as regards the trigger values for bees to take into account the new scientific development.

A draft act was submitted to Member States and will be presented to the Committee in May for a discussion and possible adoption.

5. AOB

No other points to be discussed.

A.17 Court cases.

No news on Court cases.

A.18 Endocrine disruptors:

The Commission gives a brief update on the progress with the proposal for scientific criteria for endocrine disruptors. No concrete deadlines can be given at the moment, but the Commission will keep the Committee informed.

A.19 Minor Uses:

There was no meeting of the Steering Group on the EU Minor Uses Facility since the last meeting of the Standing Committee.

The next meeting will take place on 14th April.

A.20 Interpretation Issues:

No new questions were received under this agenda point.

A.21 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 DAR and RAR (Draft Risk Assessment Report and Renewal Assessment Report)

The Commission reminds Member States that the preparation of CLH dossiers, although currently no legal obligation under Regulation 1107/2009, will become detrimental for a more efficient and transparent assessment process. Member States are urged to submit such dossier for each active substance that is not considered to be a low risk substance.

A.22 Glyphosate:

See agenda item B.05.

A.23 Exchange of information from the Pesticides 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.24 Tefluthrin - Article 56 submission by Syngenta (Germany)

Point postponed.

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

Point postponed.

A.26 Acetamiprid (new toxicological reference values) (to be noted) (Germany)

A new Rev. 10 was prepared shortly before the meeting. The note-taking is therefore postponed and Rev. 10 will be noted in May.

A.27 Straight Chain Lepidopteran Pheromones (SCLP): new compound amended Review Report (SANCO/2633/08 Rev. 9) (to be noted)

Point postponed.

A.28 Follow up to the workshop on harmonisation of risk assessment in section toxicology held in Vienna in June 2016.

In 2013 PAN has filed a complaint against the Commission concerning the procedure for setting confirmatory information requirements under Directive 91/414 and in particular in the case of the approval of 10 substances.

The decision of the Ombudsman deals with the procedure for confirmatory information under Directive 91/414 and under Regulation (EC) No 1107/2009.
The decision also calls on the Commission to review its position on the way risk mitigation measures are included in approval regulations and the way they reflect EFSA conclusions. The Ombudsman decision concerns also the Food and Veterinary Office (FVO) audits and the control exercised by the Commission on the Member States authorisations for products.

The Ombudsman requests the Commission to provide a report within the next 2 years.

Two Member States indicated that the decision underlined the importance of the EFSA conclusions. The evaluation leading to the approval focuses on one safe use. This evaluation is not the adequate base to propose Risk Mitigation Measures. Conclusions should be guarded and measured and avoid theoretical issues. One Member State indicated that the decision of the Ombudsman does not fully take into account the subsidiarity principle as risk mitigation measures are concerned. It also underlined that the decision does not take into account that an approval does not mean that the product will be on the market, it needs to pass the zonal system.

B.01 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 SANTE/11866/2015 Rev. 0)

The draft act was discussed with Member States, but no vote was taken.

Vote postponed

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance prosulfuron, as a candidate for substitution, 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/10681/2015 Rev. 1)

The draft act was discussed with Member States, but no vote was taken.

Vote postponed

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance whey 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/12354/2015 Rev. 1)

The draft was presented for vote.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance diammonium phosphate 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/12351/2015 Rev. 1)

The draft was presented for vote.

Vote taken: Favourable opinion.

B.05 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 (1) (Draft Review Report Doc. SANTE/10027/2016 Rev. 2)

The Commission introduced the draft and presented its contents. It referred to feedback already received from Member States and addressed key points. Member States expressed their positions on the draft. To facilitate further discussions, the Commission invited Member States to submit written comments, and in particular those Member States who did not support to indicate the amendments necessary to obtain their support, by 18 March 2016.

Vote postponed

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances bentazone, cyhalofop butyl, diquat, famoxadone, flumioxazine, DPX KE 459 (flupyrsulfuron-methyl), metalaxyl-M, picolinafen, prosulfuron, pymetrozine, thiabendazole and thifensulfuron-methyl

The draft was presented for vote. Three member States abstained because they do not consider that all substances contained in the proposal should get an extension of their approval.

Vote taken: Favourable opinion.

M.01 News from Food and Veterinary Office (FVO)

The Commission gave a presentation summarising the outcome of the Directorate F survey on PPP authorisation conducted in 2015, outlined the plans for an audit series on PPP evaluation in 2016 and gave feedback on the ongoing audit series dealing with the marketing and use of Plant Protection Products.

M.02 New scientific publications.

No new publications to report.

M.03 AOB

MAgPIE (Mitigation of the risk of plant protection products in the environment).

The Commission informed the Commission about a SETAC workshop on 18/19 May. In that workshop, the progress on the MAgPIE toolbox will be presented and discussed.

M.04 Date of the next meeting.

The date for the next meeting is 18-19 May 2016.