EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

sante.ddg2.g.dir(2015)4187405

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 28 MAY 2015 - 29 MAY 2015

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/a83eb4c7-8787-4b20-b81d-59c947987044Blank Link*

A.01 Summary Report of previous meetings.

The Summary Report has been uploaded on the EU Health and Food Safety website:

http://ec.europa.eu/food/plant/standing_committees/sc_phytopharmaceuticals/index_en.htm

A.02 New active substances:

1. New admissible dossiers (to be noted)

- *Purpureocilium lilacinum PL 11*

The admissibility of the dossier was noted.

2. European Food Safety Authority (EFSA) conclusions:

i Tricyclazole

A short introduction to the issues detailed in the EFSA Conclusion was provided. Comments were requested from Member States by 19 June 2015. Member States were informed that a draft review report and Regulation would be prepared ahead of the July meeting.

ii Benzovindiflupyr

Member States were informed of the availability of the EFSA conclusion.

iii Trichoderma atroviride SC1

Member States were informed of the availability of the EFSA conclusion.

iv Mandestrobin

EFSA conclusion was received and will be sent to the notifier for comments.

3. Commission draft review report and Regulation concerning the approval of:

i Cyantraniliprole

No proposal was submitted to the Committee yet as Commission is waiting for a revised conclusion as announced by the EFSA.

ii Flumetralin

Some brief background to the substance was provided. The key issues from the EFSA Conclusion were detailed and the first draft of the Review Report and Regulation were explained. Comments on these drafts were requested by 19 June 2015.

iii 3-decen-2-one

Some brief background to the substance was provided. The key issues from the EFSA Conclusion were detailed and the first draft of the Review Report and Regulation were explained. Comments on these drafts were requested by 19 June 2015.

iv Pepino mosaic virus CH2

Discussion referred to in Section B.

v Halauxifen-methyl

Discussion referred to in Section B.

vi Ethametsulfuron-methyl

No new information.

vii Sulfoxaflor

A draft review report and approval Regulation were presented together with comments provided by some Member States in advance of the meeting. The Commission intends to present a final draft for vote in July.

viii Orthosulfamuron

A Decision concerning the non-approval of the active substance was presented and Member States have been asked to comment. No comments were received so far, except for one Member State. In the meantime, the Commission has received requests to allow the extension of expiring provisional authorisations. The Commission

clarifies, that, as the substance is proposed for a non-approval, it is not possible to grant that extension.

ix Flumetralin

See sub-point A.02

x Flutianil

No new information.

4. *Chromobacterium subtsugae* PRAA4-1 (MBI-203).

This biological insecticide is not a spore forming bacterium and the cells lose viability on completion of the fermentation process, to the extent that when the formulated product is packaged, living cells are not present in the product.

The issue which data requirements (chemical or microbial) apply will be further discussed in a small Working Group on 25th June 2015.

A.03 Renewal of approval:

1. Draft Working Document Renewal Programme (doc. SANCO/11284/2012 Rev.15) (For information)

A new revision of the document has been prepared and will be uploaded on the Directorate General for Health and Food Safety (DG SANTE) website.

2. 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 (doc. SANCO/10148/2014 Rev. 4) (For information)

A new revision of the document is in preparation.

3. State of play Annex I Renewal project 2nd phase (AIR-2)

At the next meeting a proposal will be presented for the extension of the approval period for several AIR II active substances due to the current delays.

4. EFSA conclusions

i Bentazone

Member States were informed of availability of the EFSA conclusion.

ii Iprovalicarb

The EFSA Conclusion was published on 14 April 2015 and the comments submitted by the applicant on this Conclusion have been tabled. The Committee was informed

about the main issues raised by EFSA. A draft Review Report will be prepared in due course. Member States have been invited to comment by 19 June, 2015 on the documents available.

iii Triasulfuron

The EFSA Conclusion was published on 8 January 2015 and the comments submitted by the applicant on this Conclusion have been tabled. The Committee was informed about the main issues raised by EFSA. A draft Review Report will be prepared in due course. Member States have been invited to comment by 19 June on the documents available.

5. Draft Review Reports for discussion

i Flupyrsulfuron-methyl

A draft Review Report has been prepared. As the status of the classification proposal by EFSA has been clarified, the applicant has been asked for comments.

ii Thiabendazole

A draft Review Report had been prepared shortly before the March meeting. Some Member States and the notifier submitted comments on that draft. A revised draft Review Report will be prepared for the July meeting.

iii Lambda-cyhalothrin (New Reference Values to be noted)

The revised EFSA Conclusion was published in March 2015 and an updated draft review report has been uploaded on CIRCABC. The applicant has been asked to submit comments on both documents. The rationale behind the unrestricted Commission proposal outlined in the revised draft review report was presented to the Committee. Comments were requested on the draft Review Report by 19 June.

The EFSA conclusions include significantly revised toxicological reference values. Considering that EFSA received a mandate from the Commission to update within 6 months all Maximum Residue Levels (MRLs) where reference values have changed, the Commission proposes the Committee to take note of the revised reference values in this meeting. This procedure should be considered as exceptional and is to be followed in this particular case, to avoid delays with the review of the MRLs by EFSA. A few Member States asked for clarification as regards the deadline for reviewing plant protection product authorizations according to the amended reference values. It was agreed that the revised reference values will only trigger review of MRLs, while they will be applicable to review of product authorization only by the date of application of the legal act of renewal of approval.

The Committee took note of the new reference values. One Member State declined to note the revised reference values.

iv Acybenzolar-S-methyl

There is no new information regarding this active substance. The revised EFSA Conclusions may be ready in the near future.

v Amitrole

A draft Review Report has been prepared. Before any decision on the renewal of *amitrole* will be taken, EFSA has been requested to update the EFSA Conclusion on amitrole with respect to the second interim criterion as regards possible toxic effects on endocrine organs.

vi. Pyridate

Not discussed, see item B.13.

vii Flumioxazin

A mandate has been sent to the EFSA for scientific assistance as regards data on evidence that the application of flumioxazin is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods.

viii Prosulfuron

The revised EFSA Conclusion was published in March. The issues in the EFSA Conclusion were explained and the rationale provided in the draft Review Report was provided. The Committee were informed about the new comments on both the EFSA Conclusion and the draft Review Report submitted by the applicant and were told that a draft Regulation would be available for the July meeting. Comments were requested on the draft Review Report and proposal by 19 June, 2015.

ix Pymetrozine

An update on the current position was provided and the revised version of the Review Report was explained. The Committee was informed that the applicant had been given the opportunity to provide some information before proceeding with decision making. The Committee were informed that an update would be given in July.

x Metsulfuron-methyl

A draft Review Report has been prepared. Comments are requested by 19 June 2015.

xi Esfenvalerate

Interservice consultation on this proposal will be started soon. Comments received will be carefully considered before starting this consultation. One Member State indicated that it could not support the proposal given the risk to aquatic organisms.

xii Florasulam

The draft Review Report was circulated after the Standing Committee in March 2015. A Member State and the notifier submitted comments on that draft. A revised draft Review Report has been prepared. Member States are asked to submit further comments by 19 June 2015.

xiii Ferric phosphate

Discussion referred to in section B.

xiv Pyraflufen-ethyl

A draft Review Report has been prepared. Comments are requested by 19 June 2015.

xv Cyhalofop-butyl

A draft Review Report has been prepared and presented. Comments are requested by 19 June 2015.

xvi 2,4-D

The revised EFSA Conclusion was published on 11 March 2015 and the applicants already presented their comments on that Conclusion in a document that was tabled. Earlier comments had already been made available to Member States. A draft Review Report was provided to the Committee; it already contained the views by RMS Greece and the applicant. A first draft of a Regulation would be available for the July meeting although it is not intended to proceed to a vote at that meeting. Comments were requested on the draft Review Report that was circulated by 19 June.

6. Next stage of renewal programme

- Proposed Rapporteurs and Co-rapporteurs for AIR-4

Regarding the next phase of the renewal programme it was indicated that the procedure according to Regulation (EU) No 844/2012 will apply. This phase will deal with more than 200 active substances with current expiry dates of 2019-2021. A draft list of RMS and Co-RMS was prepared and circulated for commenting. Based on the comments received, a revised list will be prepared.

A.04 Confirmatory data:

i Tall oil pitch

An update on the current situation was provided. Member States were informed that a further evaluation of data was ongoing by the Rapporteur Member State, Greece. This was due to be completed by the end of July and would be circulated for comments to Member States and EFSA. A final proposal would be made once this evaluation had been completed.

ii Tall oil crude

An update on the current situation was provided. Member States were informed that a further evaluation of data was ongoing by the Rapporteur Member State, Greece. This was due to be completed by the end of July and would be circulated for comments to Member States and EFSA. A final proposal would be made once this evaluation had been completed.

iii Etridiazole (revised review report to be noted)

The revised review report as presented at the March meeting was again explained and was noted.

4 Member States did not take note of the revised Review Report as they did not consider the toxicological relevance of metabolites to be fully addressed.

iv Dithianon

During the last PAFF meeting the Commission presented a draft review report based on the confirmatory data that was received. Since Member States did not agree on the nature of the residues in processed products, the Commission is now preparing a mandate to EFSA to review this issue. The mandate will soon be sent to EFSA.

v Haloxyfop-P

The Commission explained that the situation remained unchanged and that the only way forward seems to be a restriction in rates and timing of application. It is intended to present a draft Regulation in that sense for the July meeting.

vi Chlormequat (revised review report to be noted)

A revised review report had already been presented to the Committee in January but Member States requested further time for examination. Meanwhile, the Member States that reacted agreed with the approach explained. No disagreement has been formulated and, as a consequence, the report has been noted by all Member States.

vi Buprofezin

Member States were reminded that an EFSA Conclusion is due at the end of July following the evaluation of confirmatory data. Comments were submitted after the March meeting by one Member State; other Member States were reminded that comments could be submitted with a deadline of 31 July 2015. A proposal would be made following receipt of the EFSA Conclusion, taking into account Member States' comments.

vii Pyrethrins

Member States were reminded of a recent EFSA technical report concluding the commenting phase on the first step of confirmatory data on the technical specifications. Considering its outcomes and the fact that other confirmatory data are

expected by the end of this year, the Commission proposes to the delegates to postpone the possible decision for an EFSA peer review until the assessment of confirmatory data will be completed

Member States are requested to send any comment by 19 June 2014.

viii AOB

No other points.

A.05 Article 21 Reviews:

i Diflubenzuron

As regards risk management issues listed in the Reporting Table that require further discussion, the Commission summarised the key points and reported on the comments received so far. It asked to receive feedback from more Member States, to inform its ongoing internal deliberations. Member States are asked to submit further comments by 31 July 2015.

ii Chlorpyrifos – state of the dossier

The amended endpoints as finally presented and discussed during the March meeting were taken note of in a written procedure.

A.06 Amendment of the conditions of approval:

- *Bacillus subtilis QST 713*

The active substance Bacillus subtilis is currently approved as a fungicide. The notifier informed the Commission, through the Netherlands, that the use as a bactericide was unjustly omitted from the approval decision. The use as a bactericide has already been assessed as part of the approval process and has also been included in the review report. The Commission therefore has come to the conclusion that this use was erroneously not included in the approval decision and has made the necessary amendments. The proposal can be found on CIRCABC. A vote is foreseen for the July meeting. Comments can be submitted by the 19 June 2015.

A.07 Basic substances:

1. Pilot projects: state of play

The Commission recalled the recent exchange of information on the organisation of an experts group with EFSA cooperation to proceed with development of pilot applications concerning different type of basic substances in view of the more comprehensive review of the current Guidance.

Some Member States have indicated their interest in working on the applications or provide contributions. The Commisison would recommend to promptly following the process up before the summer break to be able to organise a first meeting in September.

2. New dossiers received

New dossiers were received for sweet whey, clayed charcoal and Urtica folium.

3. EFSA Technical Reports

No new reports.

4. Draft Review Reports for discussion

i Artemisia absinthium

Interservice consultation on this proposal will be started soon.

ii Tanacetum vulgaris

Interservice consultation on this proposal will be started soon.

iii Fructose

Interservice consultation on the proposal has been launched.

iv Arctium lappa

A draft Review Report and corresponding proposal has been prepared and presented. Comments were requested by 19 June 2015.

v Sodium hydrogen carbonate

A draft Review Report and corresponding proposal has been prepared and presented. Comments were requested by 19 June 2015.

A.08 Green substances – Garlic extract (revised review report for discussion).

A revised review report is available for Member States' comments. The Commission proposes to maintain the conditions of approval of the garlic extract. Member States are requested to send their comments by 19 June 2015.

A.09 Exchange of views and possible taking note of the following Guidance Documents:

1. Draft Guidance Document (GD) on assessment of negligible exposure of an active substance in a plant protection product under realistic conditions of use (points 3.6.3

to 3.6.5, and 3.8.2 of Annex II to Regulation (EC) No 1107/2009) (doc. SANCO/12096/2014) (for discussion)

The Commission presented a draft Guidance document (GD) and asked for comments from Member States by 19 June 2015.

The draft GD was developed by an expert group appointed by Member States which met 5 times from September 2013 onwards. Previously Member States had sent preliminary input regarding how to address negligible exposure. Discussions in the expert group were intense, no full consensus was achieved but the present draft is the best compromise achievable. The Commission reminded previous discussions at this Committee, where it was stated that few substances classified as carcinogenic or toxic to reproduction category 1 are still on the market, while some substances falling under the interim criteria for endocrine disruptors would fall under these provisions. The Commission also reminded that active substances approved under the provisions of negligible exposure would be candidates of substitution, by default.

The GD is intended to be adopted as a Commission Notice. Internal procedures are initiated. A targeted stakeholder consultation is planned before the summer

2. European Food Safety Authority (EFSA) Guidance document on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014; 12(10):3874 (to be noted)

The Standing Committee took note of this Guidance Document (doc. SANTE/10832/2015). The guidance document is applicable to applications submitted after 1st January 2016. For the approval of active substances under Regulation (EC) No 1107/2009, the risk assessment on residents and bystanders cannot be fully considered until a procedure for the derivation of the AAOEL (Acute Acceptable Operator Exposure Level) and higher risk assessment schemes, identified as missing by the Standing Committee, are available.

On the draft concept paper (terms of reference) to develop the AAOEL, the Commission and the United Kingdom thanked the Member States who submitted comments. The United Kingdom invited Member States to reflect on the "naming" of the toxicological reference value, and on the relation between sensitization vs. local effects. Additional comments of Member States to the United Kingdom are welcome until 19 June 2015. A revised document will be provided in future meetings for discussion. EFSA asked for clarification if this reference value will be applicable for approvals and authorisations.

3. Draft Guidance document on the Interpretation of the Transitional Measures for the Data Requirements for Chemical Active Substances and Plant Protection Products according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (doc. SANCO/11509/2013 Rev. 5) (for discussion)

A new revision has been prepared to assure that all applications for re-authorisation of plant protection products for AIR-2 active substances can be treated according to the old data requirements. In the current revision the text has been aligned with the final text of the Regulation amending Regulation (EU) No 284/2013.

4. Draft Template to be used for the List of Endpoints (SANCO/12483/2014 Rev. 3) (to be noted)

In the template for the List of Endpoints for the microorganisms the OECD-numbering has been added. The document was noted.

5. Draft Guidance document concerning the parallel trade of plant protection products (doc. SANCO/10524/2012 Rev. 5) (to be noted)

At the March 2015 Committee Meeting, an amendment to the Guidance Document on Parallel Trade was proposed in order to take into account the judgment in the case C-108/13 in relation with parallel trade of parallel traded products.

The Commission confirmed the need to amend the guidance. Comments were received from different delegations. Some Member States did not consider that it was needed to amend the guidance as the judgement pertains to the implementation of Directive 91/414/EC and not Regulation (EC) No 1107/2009.

Concerning the parallel trade of products not covered under Article 52, the Commission confirmed that Articles 34 to 36 TFEU: examination procedures for parallel trade permits, should be proportionate to the objectives.

The Commission indicated that it was not the intention to modify other parts of the guidance as an agreement on those parts was reached at that time of the adoption of version 4.

The Commission will prepare a new amended version for the next meeting of the Committee taking into account comments of delegations.

6. Draft Guidance document on Semiochemical Active Substances used in Plant Protection Products (doc. SANTE/12815/2014 Rev. 4)

An updated revision will be circulated for commenting.

A.10 Notifications under Article 53 of Regulation (EC) No 1107/2009 (to be noted):

Chloropicrin (Belgium)
1,3-dichloropropene (Belgium)
Ethylene (Belgium)
Epoxiconazole (Belgium)
Prothioconazole (Belgium)
Metconazole (Belgium)
Tebuconazole (Belgium)
Epoxyconazole (Belgium)
Cyproconazole (Belgium)
Propiconazole (Belgium)
Azoxystrobin/Cyproconazole (Bulgaria)
Trifloxystrobin/Cyproconazole (Bulgaria)

Lime sulphur (Czech Republic)
Aureobasidium pullulans strains DSM 14940 and DSM 14941 (Germany)
Azadirachtin (Germany)
Dimethoate (Germany)
Lambda cyhalothrin (Germany)
Lime sulphur (Germany)
Potassium hydrogen carbonate (Germany)
Spinosad (Germany)
Spirotetramat (Germany)
Spirotetramat (Germany)
Thiamethoxam (Germany)
Thiram (Germany)
Carfentrazone-ethyl (Denmark)
Azadirachtin (Denmark)
Thiamethoxam (Denmark)
Clothianidin (Denmark)
Captan (Denmark)
Asulam (Denmark)
Flurprimidol (Denmark)
Abamectin (Estonia)
Clothianidin/Beta-cyfluthrin (Estonia)
Thiamethoxam/Metalaxyl-M/Fludioxonil (Estonia)
Mesosulfuron/Iodosulfuron (Estonia)
Dimethoate (Spain)
Famoxadone/Cymoxanil (Spain)
Mefenoxam/Mancozeb (Spain)
Tembotrione (Spain)
Clethodim (Spain)
Trinexapac (Spain)
Rescalure (Spain)
Spirotetramat (Finland)
Cyprodinil/Fludioxonil (France)
Asulam (France)
Cyazofamid (France)
Oxadiazon (France)
Spinosad (France)
Acibenzolar (France)
Aclonifen (France)
Asulam (France)
Azadirachtin (France)
Chlorpropham (France)
Chlorpyrifos (France)
Lambda cyhalothrin (France)
Lime sulphur (France)
Metobromuron (France)
Pendimethalin (France)
Spinosad (France)
Tefluthrin (France)
Bentazone (Greece)
MCPA (Greece)

Straight Chain Lepidopteran Pheromones (Croatia)
Captan (Croatia)
Clomazone (Croatia)
Phosmet (Croatia)
Pyroxsulam (Croatia)
Azadirachtin (Croatia)
Potassium hydrogen carbonate (Croatia)
Paraffin oil/Copper oxide (Croatia)
Aclonifen (Hungary)
Kasugamycin (Hungary)
Triclopyr (Hungary)
Propanil (Italy)
Quinclorac (Italy)
Spinosad (Italy)
Acetamiprid (Italy)
Clofentenzine (Italy)
Zoxamide/Cymoxanil/Fosetyl (Italy)
Paclobutrazol (Italy)
Pendimethalin (Italy)
Phosmet (Italy)
Pretilachor (Italy)
Pseudomonas chlororaphis (Italy)
Tebuconazole/Chlorothalonil (Italy)
Terbacil (Italy)
Tricyclazole (Italy)
Ipsdienol/Cis-verbenol/2- Methyl -3-buten-2-ol (Latvia)
Ioxynil (Latvia)
Asulam (the Netherlands)
Prochloraz (the Netherlands)
Thiram (the Netherlands)
Cyazofamid (the Netherlands)
Potassium bicarbonate (the Netherlands)
Diflubenzuron (the Netherlands)
Pyriproxyfen (Portugal)
Spinetoram (Portugal)
Aureobasidium pullulans strains DSM 14940 and DSM 14941 (Portugal)
1,3-dichloropropene (Portugal)
Quinclorac (Portugal)
Flonicamid (Portugal)
Acibenzolar-S-methyl (Portugal)
Imazamox (Portugal)
6-benzyladenine (Portugal)
Mandipropamid (Slovenia)
Spinosad (Slovenia)
Azadirachtin (Slovakia)
Bifenthrin (Slovakia)
8-methyl-2-decanol propanoate (Slovakia)
Chlorpyrifos (Slovakia)
Fatty acids (Slovakia)
Oxyfluorfen (Slovakia)

Pyrethrins (Slovakia)
Tefluthrin (Slovakia)
Asulam (the United Kingdom)
Garlic extract (the United Kingdom)

The Committee took note of the notifications submitted by Belgium, Bulgaria, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, Greece, Croatia, Hungary, Italy, Latvia, the Netherlands, Portugal, Slovenia, Slovakia and the United Kingdom.

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

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

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

Furthermore, the Commission pointed out that for minor uses Member States should make use, whenever possible, of the provisions laid down in Article 51 of Regulation (EC) No 1107/2009. Member States should also take into account efficacious alternatives which are available among bio-pesticides and bio-control agents, to promote low input techniques as required by Directive 2009/128/EC.

A.11 Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (to be noted).

No notifications submitted.

A.12 Notifications under Article 36(3) of Regulation (EC) No 1107/2009 (to be noted).

Two notifications have been submitted.

One notification referred to a national risk assessment which was considered more valid than the assessment of the zonal rapporteur Member State. The Commission reminded that this does not seem to be a valid reason for refusing to authorise under the provisions of Article 36.

A.13 Notifications under Article 53 of Regulation (EC) No 1107/2009 (to be noted).

Please see A.10 above.

A.14 Sustainable Use Directive (Directive 2009/128/EC):

1. National Action Plans (NAP) Report

The Commission informed that the report on the information transmitted through the National Action Plans in compliance with Article 4 of the Directive 2009/128/EC is expected to be ready for transmission with all translated versions, during the summer, hence it will be presented to the next Council presidency (Luxembourg). However, the FVO detailed analysis should be published in the coming weeks on the Directorate General for Health and Food Safety (SANTE) webpage.

2. Harmonised standards for inspection of Pesticide Application Equipment (PAE)

The Commission informed that new standards for inspections of sprayers in use have been adopted by CEN and ISO (EN ISO 16122-1 to 16122-4) following the previous mandate sent by the Commission to the standardisation body. A Commission Communication citing these standards is expected to be published in the Official Journal (part C) by 12 June 2015, by which these standards are becoming harmonised standards under Union harmonisation legislation. Information and links will be provided via the SANTE website (section on SUD).

3. Better Training for Safer Food (BTSF) Projects ongoing workshops

The Commission informed about the ongoing BTSF Training funded by SANTE, which is focused on inspection of standards. A total of 6 training sessions are foreseen during 2015 and 2016. They will be performed in Barcelona (ES), Braunschweig (DE), Torino (IT) in facilities which allow practical experience. Member States will be contacted via the national contact point for BTSF for nominating their experts to be trained.

4. State of play

No discussion.

A.15 News from European Food Safety Authority (EFSA)

1. Guidance development

EFSA presented the new guidance document. It was agreed to postpone the taking note process until the full soil package is published.

EFSA indicated the new opportunities for involving Member States in the guidance development through the Pesticides Steering Network and highlighted that comments on technical and scientific issues should be submitted during the guidance development, keeping the consultation under the PAFF noting process restricted to Risk Managers issues. The Commission supported EFSA.

EFSA also mentioned that, following the adoption of the Scientific Opinions on Non-target plants and invertebrates, they are discussing with the Commission the details for the Risk Management consultation on the protection goals.

2. Pesticides Steering Network (PSN)

Following the PSN meeting, EFSA is waiting for the Commission to confirm a mandate on the Terms of Reference for the three guidance documents discussed in February. EFSA is also awaiting European Crop Protection Association (ECPA) input regarding a workshop on high tier studies. EFSA is assessing the services provided to applicants by EFSA and the RMSs. A PSN teleconference may be scheduled in June/July.

3. Original Dossiers for AIR III

EFSA indicated that it has received a Renewal Assessment Report (RAR) with the indication that the original dossier is not available to the RMS. EFSA and Member States require access to all relevant studies, consequently a solution is needed for this and other cases. When the RMS do not have access to the original dossier, they should check if other Member States have the original dossier and liaise with the Member State to ensure that all relevant studies are available for the RAR and peer-review.

A.16 Report from working groups:

1. Authorisation database

A summary of the recent key activities and developments was given. Member States were informed that the system should be now referred to as the 'PPP Application Management System'; the authorisation database is just a single component of the System which is also an application management tool. The following updates were given:

- The System was launched for use on 20 February 2015; activities are now focussed on ensuring that stakeholders have access and begin using the System before use is made mandatory in 2016.

- A training event was held for Member States on 7 and 8 May 2015. The event was successful and feedback has been taken into account leading to amendments to the System. Presentation and materials from the training had been made available on CIRCABC for all Member States to use.

- A small Working Group will be set up to ensure smooth implementation – Member States were reminded to submit interest in being part of the Working Group.

- Member States were informed that on 28 May an e-mail had been sent to all Member States to initiate the data migration exercise from national databases.

- The next stages of development were underway; these include development of the Article 53 platform and making changes based on the Member State feedback.

- Further training would be scheduled for relevant stakeholders.

2. Low risk

The next meeting is scheduled for 23-24 June 2015.

3. Zonal Workshop

The Workshop on Zonal Evaluation, Mutual Recognition and Re-authorisation will be organised from 2-4 June 2015 and is hosted by Ireland. An invitation, outline, agenda and background documents for the workshop have been circulated and put on CIRCABC.

The workshop will be structured in plenary and break-out group sessions to allow more interaction between the participants.

Two participants per Member State will be reimbursed. Industry and other stakeholders will be invited as well. Total number of participants will be around 70 people.

A.17 OECD

No new activities.

A.18 Bees:

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

As requested by the Commission, EFSA launched an open call to collect any new scientific data relevant to the evaluation of the risk to bees from uses of the three neonicotinoid insecticides.

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

The decision-making on the way forward within the Commission services is on-going. European Crop Protection Association (ECPA) reiterated its comments on this subject. A letter received recently on this topic is available in CIRCABC.

3. 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.

The decision-making on the way forward within the Commission services is on-going.

4. EU Conference "Field studies and Monitoring Activities carried out at National level on the effect of Pesticides on Bees and other Pollinators" (MAPoB) –
9-11 September, Germany

The Commission informed that the conference will take place in Bonn and not in Berlin as indicated in previous communications; the Commission is investigating the possibility to reimburse 2 experts from Member States. A Member State requested if it is possible to attend the conference with a higher number of experts. The Commission will investigate and additional informations for Member States will be circulated by e-mail.

5. European Academies Science Advisory Council report "Ecosystem services, agriculture and neonicotinoids"

On 9 April 2015, the European Academies Science Advisory Council (EASAC) published a report on neonicotinoids. The report covers an assessment of more than 100 peer-reviewed studies and goes beyond the effects for honey bees. Neonicotinoids are examined and criticized for their impact on ecosystem services (on pollination service but also on natural pest control, on soil ecosystem and on biodiversity).

The report was requested by the Commission Chief Scientific Adviser in 2013.

The main conclusions are the following:

1. Widespread prophylactic use of neonicotinoids may have severe negative effects on non-target organisms that provide ecosystem services including pollination and natural pest control.

2. There is scientific evidence for the existence of sublethal effects if very low levels of neonicotinoids are administered over extended periods to non-target beneficial organisms. These should be addressed in EU approval procedures.

3. Current practice of prophylactic usage of neonicotinoids is inconsistent with the basic principles of integrated pest management as expressed in the EU's Sustainable Pesticides Directive.

4. Widespread use of neonicotinoids (as well as other pesticides) constrains the potential for restoring biodiversity in farmland.

The report is available online and uploaded in CIRCABC. It will be part of the scientific information to be assessed by EFSA.

6. IUCN Red list of bees

The red list of bees was released by the International Union Conservation Nature (IUCN). The publication belongs to a bigger project "The European Red List" (on the review of the conservation status of about 6,000 European species according to IUCN regional Red Listing guidelines). It identifies those species that are threatened with extinction at European level – so that appropriate conservation action can be taken to improve their status.

The report is available online and uploaded in CIRCABC.

7. New Scientific publication: Rundlof M. et al., Seed coating with neonicotinoid insecticide negatively affects wild bees, Nature

Sweden requested to share this new article published in Nature in the framework of the Standing Committee.

The publication reports huge field studies on wild bees with strong statistic weight (8 pairs of landscapes sown respectively with spring oilseed rape treated seeds coated with Elado (clothianidin and beta-cyfluthrin + fungicides) vs untreated oilseed rape (treated only with fungicides without insecticides)

The authors concluded:

1. Clothianidin has a direct impact on density of wild bees;
2. Treated fields are directly correlated with reduction of solitary bee nesting (Osmia bicornis);
3. Seeds treated with clothianidin are negatively related to colony growth and reproduction of bumble bees;
4. No direct correlation is demonstrated between Clothianidin treatment and honeybees colony strength. One suggestion is to explain the fact that a longer term study is needed to find effects on honeybees. Therefore the authors do not exclude long-term effect on honey bees in any case.

This article will be part of the scientific information to be assessed by EFSA.

08 AOB

- "Beehave" Statement from EFSA is currently being published. EFSA gave a presentation on the topic.
- The Commission informed the Committee on the publication of the second report of the Epilobee project co-financed by the Commission. The report produced by the EURL is available online and uploaded on CIRCABC.
- The Commission informed the Committee on the recent "National strategy to promote the health of honey bees and other pollinators" from the Pollinator Health Task Force of the White House, published on 19 May 2015.

A.19 Court cases:

The applicant PAN decided to withdraw its action.

A.20 Endocrine disruptors:

1. Impact assessment

The Commission informed about the on-going impact assessment. On communication aspects, up-to-date information can be found via http://ec.europa.eu/health/endocrine_disruptors/policy/index_en.htm, including information on the roundtables with stakeholders, Member States, and Members of the European Parliament, as well as on the conference planned for the 1 June 2015.

The 1st study (screening of substances falling under each of the 4 options to define the criteria) is on-going. The 2nd study (assessing the positive and negative impacts on a wide range of sectors) is in an early planning phase. It cannot be started before the screening has been completed.

2. Interim criteria

The Commission informed that the implementation of the 2nd interim criterion in the current decision-making needs to be discussed in up-coming meetings, and suggested following a similar approach as the one taken for the impact assessment.

A.21 Minor Uses:

The Commission informed about progress in the establishment of an EU Minor Uses Co-ordination Facility, hosted by the European and Mediterranean Plant Protection Organisation (EPPO) and jointly funded by the EU and by the governments of France, Germany and the Netherlands.

The mission of the Facility is "to enable farmers in the EU to produce high quality crops by filling minor uses gaps through efficient collaboration to improve availability of chemical and non-chemical tools within an Integrated Pest Management (IPM) framework." The Steering Group held its first meeting on 29 April 2015, and agreed to start the process of recruiting a coordinator to lead the work of the Facility. The advertisement for the post of a coordinator was published on 6 May on the EPPO website and interlinked on the SANTE website. More information can be found on the EPPO or DG SANTE website.

A.22 Interpretation issues :

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

Discussion postponed.

2. Questions and answers

The Commission presented two new entries in the Question and Answer document, one related to the definiton of Plant Protection Products (PPP) in Article 2 and the second related to placing on the market of PPP in Article 28. In addition an amendment of an existing Q and A was presented in relation to labelling of treated seeds in Article 49. Comments are welcome until 19 June 2015.

A.23 Status of harmonised classifications under Regulation (EC) No 1272/2008:

Discussion postponed.

A.24 Glyphosate:

- State of the dossier

The Commission reported on the classification of glyphosate and other active substances by the International Agency for Research on Cancer (IARC), the public reaction by the German Federal Institute for Risk Assessment (BfR), and the Commission mandate to EFSA in this regard. Member States and EFSA shared information on their requests to IARC for more detailed information.

A.25 EFSA Scientific Opinion on the developmental neurotoxicity potential of acetamiprid and imidacloprid.

The Commission acknowledges the need for the development of integrated in vitro neurotoxicity testing strategies complementary to in vivo assays included in the OECD TG 426 to screen for developmental neurotoxicity potential. Such need was already highlighted by the recommendations in the EFSA Opinion published in 2014 and by international scientific discussions published in the scientific literature in 2015. The Commission intends to propose/support activities in this respect at OECD level. Appropriate integrated screening testing strategies may then be included in the data requirements for plant protection products and review of the developmental neurotoxicity potential of acetamiprid, imidacloprid (and possibly of other neonicotinoids) may be triggered if necessary.

A.26 Imidacloprid (revised review report for note taking):

Assessment of confirmatory information and review of the aquatic risk assessment (Article 21 Regulation (EC) No 1107/2009)

The revised review report was noted.

A.27 Note taking procedures.

Two Member States have submitted comments following the presentation of the discussion paper in March. One Member State is particularly concerned about the legal basis for the procedure.

The Commission reiterates that the note-taking is an informal procedure, which is intended to be a pragmatic approach in cases where there is no need for a formal procedure under comitology.

In the absence of further comments, the Commission considers the document which was uploaded on CIRCABC in March as final.

A.28 Dialogue event on risk assessment of active substances in plant protection products.

The Commission reported on the event that took place on 24 April 2015. For details, it referred to the Summary Report and a Communication issued by the German Federal Institute for Risk Assessment (BfR), which are both publicly available. The Commission thanked all participating stakeholder organisations, Member States and agencies, and in particular those who contributed with experts as panellists.

A.29 Isopyrazam – deadline for submission of confirmatory information.

Point withdrawn.

A.30 Topramezone – new information submitted by the applicant.

Point withdrawn.

A.31 Study on trade of illegal and counterfeit pesticides – discussion of the recommendations.

The Commission reminded Member States that the full report of the Study on trade of illegal and counterfeit pesticides is on CIRCABC.

The Commission made a presentation of the best practices and recommendations contained in the report. The recommendations include the following:

- More controls at borders are needed;
- Best practices of other MS should be used;
- Cooperation between Customs and PPP authorities is a key to success;
- There is a need to enhance legal certainty and clarify provisions of the Regulation;
- Increase of testing capacity for PPP is needed.

A.32 Interzonal workshop on 'harmonisation of risk assessment in section toxicology'.

Member States were reminded that the 'Interzonal Workshop on harmonisation of risk assessment in toxicology' was due to be held in Vienna on 23-24 June. The workshop would be attended by representatives from Member States, Industry and EFSA. The Commission thanked Austria for their work in organising this very worthwhile event.

A.33 Metam - new information submitted.

The rapporteur Member State for metam has communicated to the Commission that new data shows the need for a review of the residue definition, with a view to taking

into account the impurity DMTU. The issue should also be deepened with respect to the necessity to launch a comprehensive review with respect to the environmental risk of the impurity DMTU which had already been subject to an evaluation in the previous review concluded by EFSA in 2012.

EFSA confirmed the possibility of taking the need to revise residue definition and consumer risk assessment into account in the review of MRLs under Article 12 of Regulation (EC) No 396/2005.

The Commission proposed to follow up on the possible need for a comprehensive review under Article 21 deepening on the new evidence available. RMS was asked to provide more detailed analyses to the Commission.

A.34 EFSA Guidance Document on protected crops:

Follow-up discussion with Member States on feasibility of current application date (1/05/2015) for product authorization. One Member State requested to postpone the application date because the necessary models are not ready for use.

The Commission agreed that in the current specific case, exceptionally, the application date may be postponed, as it was premature. Due to the short notice of the request, the note taking of the amended deadline should take place in July.

A.35 EFSA Guidance Document on DT50 - Letter from European Crop Protection Association (ECPA).

The European Crop Protection Association (ECPA) was of the opinion that the application of this guidance document (GD) as from 1.5.2015 should be delayed until 1.1.2017, as to allow for the generation of new field studies should this be requested by the evaluators.

The Commission disagreed and explained that the work on this topic already started in 2010. Moreover, this GD is a key element for the correct functioning of the new Focus Groundwater II GD which in any case becomes of application on 1.5.2015. It was therefore logical and important to ensure coherence.

The Commission believes that cases where a substance or a product would fail to be approved on the basis of the new DT50 GD must be exceptional. It recalls also that this GD, as all others, should only be applied on new dossier submissions for approval or authorisation and not on assessments already in the pipeline.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance terpenoid blend QRD 460, 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/00134/2015 Rev. 3)

The Commission presented the final text for vote.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance fenhexamid 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. SANCO/11960/2014 Rev. 2)

The Commission presented the final text for vote.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance sulfosulfuron 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. SANCO/12744/2014 Rev. 2)

Two Member States did not support the proposal as it did not include a requirement for confirmatory data regarding the risk to ground water. Four Member states did not support the proposal given the risk for leaching to the groundwater.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of Artemisia vulgaris as a basic substance 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. SANCO/12898/2014 Rev. 0)

One Member State did not support the approval as it considers that ways should be found to approve this type of product as a basic substance.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance lecithins 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. SANCO/12798/2014 Rev. 2)

One Member State did not support the approval due to the lack of a risk assessment for non-target arthropods.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance Salix cortex 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. SANCO/12173/2014 Rev. 3)

Two Member State did not support the approval as they consider that Salix spp cortex should be regarded as a regular active substance instead of a basic substance.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance vinegar 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. SANCO/12896/2014 Rev. 1)

One Member State did not support the approval given the similarity to acetic acid, which is approved as a regular active substance.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance Pepino Mosaic Virus strain CH2 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/10387/2015 Rev. 1)

One Member State did not support the proposal because it does not agree that the active substance is a low risk substance.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance halauxifen-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 Implementing Regulation (EU) No 540/2011 (Draft Review Report Doc. SANTE/10406/2015 Rev. 1)

The Commission presented the final text for vote.

Vote taken: Favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance ferric 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 the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report Doc. SANTE/10385/2015 Rev. 1)

The Commission presented the final text for vote.

Vote taken: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance sulfoxaflor 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/10665/2015 Rev. 1)

Four Member States did not support the proposal as the use was not restricted to glasshouses, two Member States did not support the proposal because of the risk to groundwater, two Member States did not support the proposal as it is overly restrictive.

Vote taken: Favourable opinion.

B.12 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 timelines for submission of confirmatory information concerning the active substance isopyrazam

Two Member States are against the approval of the active substance and therefore do not support an amendment of the timelines.

Vote taken: Favourable opinion.

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance pyridate 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. SANCO/12747/2014 Rev. 2)

The Commission proposed to renew the approval of pyridate.

Vote taken: Favourable opinion.

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance topramezone, 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. SANCO/10168/2014 Rev. 0)

Some Member States did not support the proposal because of the possible risk to groundwater. Other Member States did not support the proposal as it contains too many restrictions.

As the discussion showed that no qualified majority in favour of the proposal would be reached, it was withdrawn from a vote.

Vote postponed

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

No news presented.

M.02 New Scientific Publications.

No new publications were presented under this point.

M.03 AOB

1. Phosphonic acid inorganic metabolite (DE)

Discussion postponed.

2. Commission's position regarding the substances of concern, where new evaluations/facts are provided (COM's reply to the letter from the French Government) (FR)

The Commission explained its position, as set out in a letter sent to France.

3. Impact of the "new" position of the Commission regarding the vote of MRLs for new active substances: how to deal with Regulation (EC) No 1107/2009's Article 37(3) for representative products and uses? (FR)

Discussion postponed.

4. Access to Commission documents under Regulation (EC) No 1049/2001: some MSs' documents are requested by EU legislation/regulations and the data they contain are always published in one way or another (ex. Regulation (EC) No 1185/2009 or EU MRL monitoring program). Should requests to access the original MS data be considered? (FR)

The Commission indicated that the Member State which is author of the document is consulted with a view to assessing whether an exception to paragraph 1 or 2 of Article 4 of Regulation (EC) No 1049/2001 is applicable.

5. Possible need for the amendment of an endpoint for epoxiconazole (BE)

Discussion postponed.

6. New greenhouse operator exposure model (DE)

Germany makes the meeting aware of a new greenhouse operator exposure model under development. Member States are invited to consult the documentation provided by Germany and to provide comments, if appropriate.

7. Two applications by different applicants concerning the same active substance submitted to different Member States (EL)

The Commission asks the two Member States in question to provide more information after the meeting, and will put the topic on the agenda of another meeting, if appropriate.

4. Date of the next meeting: 13/14 July (confirmed).