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 10 DECEMBER 2015 - 11 DECEMBER 2015

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/78ef083e-1ca8-4e14-b025-b8fb0d81dbb4*

A.01 Summary Report of previous meetings.

Member States were informed that the report from July was almost ready for publication and the October report was under preparation.

A.02 New active substances:

1. New admissible dossiers (to be noted)

None to report.

2. European Food Safety Authority (EFSA) conclusions

i. *Beauveria bassiana* strain 147
ii. *Beauveria bassiana strain* NPP111B005
iii. *Saccharomyces cerevisiae* strain LAS02

Member States were made aware of the EFSA Conclusions that were now available for these substances

3. Commission Draft Review Report and Regulation concerning the (non-) approval of:

i. *Cyantraniliprole*

Member States were informed of the further comments received on the draft review report. Comments received mainly refer to the groundwater risk assessment and the need to set confirmatory data requirements.

One Member State indicated they could not support approval of cyantraniliprole due to the risk to groundwater.

ii. *Tricyclazole*

Member States were informed that the inter-service consultation concerning the non-approval had been finalised. An application to consider approving tricyclazole via Article 4(7) had been received from the applicant but the Commission explained that this was not appropriate in this case.

A Technical Barrier to Trade notification was due to be completed in late December. A vote for non-approval was foreseen in January 2016.

iii. *Beta-Cypermethrin*

A revised draft of the review report (revision 1) was explained to the Committee. Changes had been made to explain a number of open areas identified by EFSA and to amend the wording of the confirmatory requirement with regards to bees. Further minor changes were foreseen ahead of finalisation.

Member States were asked to provide further comments by 6th January 2016.

iv. *Flutianil*

The EFSA conclusion contains a proposal to classify the substance as carcinogenic and toxic for reproduction category 2. The substance would therefore fall under the interim criterion for endocrine disruption. As the classification process by the European Chemicals Agency (ECHA) is ongoing and opinion of the Risk Assessment Committee is expected for the first quarter of 2016, the Commission will not proceed with a proposal for the time being.

v. *Trichoderma atroviride SC1*

The Commission noted that the EFSA conclusion identified a large part of the risk assessment as not finalised based on the absence of information which was not requested from the applicant as it is not relevant for decision-making.

Taking into account the assessment of the Rapporteur Member State (RMS) France and the discussions of the experts in the peer review, a review report and draft Regulation for approving the substance as low risk substance were presented to the Committee. Member States are invited to comment by 6th January 2016.

vi. *Acetochlo*r - withdrawal of the application from the review process (to be noted)

The applicant for acetochlor withdrew its application. Member States took note of the letter from the rapporteur Member State (RMS) Malta confirming the withdrawal.

vii. *Pinoxaden (point added to original agenda)*

The Commission was requested by several Member States to reintroduce this substance in the agenda.

The vote on the approval of this new active substance was postponed in March 2014 as several Member States did not support the proposal due to the possible leaching of metabolites into groundwater. In addition a Member State did not support the proposal due to the still pending classification of pinoxaden under Regulation (EC) No 1272/2008.

Meanwhile the RMS has submitted a dossier for classification to ECHA which does not recommend classification of pinoxaden. The commenting on this proposal within the Risk Assessment Committee procedure ended on the 16th of November 2015.

Member States were requested to indicate support of approval of this active substance to Commission by 6th January 2016.

As there seems to be substantial concerns from Member States about the safety of the substance, the prolongation of provisional authorisation for pinoxaden does not seem to be justified for the moment and the Commission will not produce a draft decision in that respect.

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. 5) (For information)

Member States were made aware of the latest version of this document.

2. State of play AIR (Annex I Renewal Project)

Member States were informed that for a number of substances, an additional extension of the approval period would be required in order to complete the assessment and the procedure for renewal.

3. EFSA conclusions:

i. *Thifensulfuron*

The Commission resumed the main issues deriving from the EFSA conclusions of July 2016. Internal examination is ongoing with respect to a possible option to allow time for submission of confirmatory studies on toxicological mechanism of action and profiles of some potentially relevant metabolites.

The RMS asked the Commission to consider that the notification of proposal for classification was submitted to ECHA in October 2015 and should be duly assessed and finalised before any decision is taken.

The Commission asked Member States for comments by 15 January 2016.

ii. *Picolinafen*

The Commission presented the main outcomes from the EFSA conclusions of November 2015. Internal examination is ongoing.

The Commission asked for comments from Member States by 15th of January 2016.

iii. *Glyphosate* (update and new reference values and endpoints discussed in section Pesticide Residues to be noted)

EFSA presented the key points on the peer review of glyphosate.

The Commission underlined that the EU system for the regulation of Plant Protection Products (PPP) is considered the strictest worldwide, and that the evaluation of glyphosate has followed a stringent process that is thorough, robust and transparent. It thanked Member States and EFSA for their work on this dossier and expressed its confidence in the process and the work of the experts in Member States and EFSA. The Commission has taken note of the EFSA Conclusion and is currently analysing the outcome of the peer review and possible next steps. It drew attention to several documents on CIRCABC.

Several Member States reported high political and media interest in glyphosate.

The Committee took note of the revised toxicological reference values (ADI (Acceptable Daily Intake), ARfD (Acute Reference Dose), AOEL (Acceptable Operator Exposure Level) as proposed in the EFSA Conclusion.

4. Draft Review Reports for discussion:

i. Thiabendazole (New Reference Values to be noted)

In the conclusion on thiabendazole an acute reference dose is proposed by EFSA together with a lower AOEL. The ADI remains at the same level.

It is therefore considered necessary to start the review of the consumer risk assessment for this substance for all EU MRLs before finalisation of the renewal procedure.

The meeting took note of the new toxicological reference values in order to review the consumer risk assessment under Regulation (EC) 396/2005.

ii. Acibenzolar-methyl

The draft review report for renewal of approval was presented. The draft proposal include provisions for Member States to pay particular attention to and a request for confirmatory information. Comments are welcome by 15th January 2016. The proposal may be scheduled for vote at the next Committee meeting in January.

iii. Amitrole

The Commission presented the proposal for withdrawal of approval due to several concerns highlighted in the EFSA conclusions. In particular, amitrole does not meet the approval criteria because EFSA proposes to classify it as toxic for reproduction category 1B; amitrole is identified as an endocrine disruptor according to the interim criteria; the groundwater risk is not acceptable in all scenarios; a high risk to operators, workers, bystanders and resident is identified. One Member State questioned whether it is necessary to refer the Guidance Document (GD) on negligible exposure in the proposal. Due to procedural issues, the proposal cannot be scheduled for vote before the meeting in March-May 2016.

The Commission asked for comments from Member States by 15th January 2016.

iv. Flumioxazin

The Commission informed that EFSA continues to work on the mandate 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.

Furthermore the applicant was requested to provide an assessment of negligible exposure.

v. Pymetrozine

Member States were provided with an update on how this file was proceeding. (Along with flupyrsulfuron-methyl; see point 4 xii.)

The RMS had been asked to carry out an evaluation of the additional information with a deadline of 22nd January 2016. EFSA would then arrange the necessary peer review.

Further updates on progress would be given to the Committee in future meetings, as appropriate.

vi. Cyhalofop-butyl

Discussion postponed until next meeting.

vii Metalaxyl-M

The Commission proposed a non-renewal of this active substance mainly as some data for an impurity is missing.

Several Member States indicated support for renewal of this substance given the setting of confirmatory data requirements. This is under internal discussion in the Commission.

The Commission informed the meeting of several letters of support for the substance received from various growers associations.

viii. Triasulfuron

The Commission recalls that the review report presented to the Committee still takes the form of a non-renewal. The Commission is willing to explore whether MS, in their role of risk managers, would agree to set themselves the toxicological reference values and finalise the human exposure assessment. In that case however, there should be a large consensus before move in that sense. Some Member States have already commented while others were invited to do so by 15th January 2016.

ix. Bentazone

The Commission proposed a restricted renewal of this active substance at the last meeting. Comments from several Member States were received. These comments allow reconsidering the proposed decision but first an exercise will be made to see which of the current EU MRLs are impacted by missing data.

One Member State indicated they cannot support renewal due to the findings of this substance in the national monitoring programs for groundwater.

Member States were requested to comment on the discussion on the technical specification by 13 January 2016.

x. Isoproturon

Member States were informed that given the concerns identified in the EFSA Conclusion, a proposal was made for non-renewal of approval. The inter-service consultation would be initiated followed by a TBT notification. Member States were made aware of correspondence received from the applicants.

xi. Famoxadone

The review report will be presented during the Standing Committee of Plants, Animals, Food and Feed (PAFF) meeting in January 2016.

xii. Flupyrsulfuron-methyl (point added to original agenda)

See point A.03 4, v.

A.04 Confirmatory data:

i. Epoxiconazole

The draft review report presented follows as much as possible the EFSA conclusion. The outstanding point is the LT risk to herbivorous birds, which is close to but still below the trigger of acceptability. Remarks have already been formulated by from some Membere States but not yet from RMS Germany. Further comments are expected by 16.1.2016

ii. Bifenthrin

No review report is available. The Commission informed that EFSA, in particular, questions the recovery of non-target arthropods (NTA) in field. Other issues seem to have been adequately addressed. It also informs that the biomonitoring exercise is ongoing and might soon enter the commenting phase

iii. Buprofezin

Member States were given an update on the state of play with regards to Member State positions on the use of the Margin of Exposure (MoE) approach in order to consider the aniline issue. There were a number of Member States who would not support the use of MoE and a number who would.

Member States were asked to consider this matter further and to indicate their positions by 6th January 2016. Some Member States had already submitted comments with regards to the MoE approach.

A further discussion would be held in January following receipt of Member States' positions.

iv. Dodine

The EFSA conclusion regarding the peer review of confirmatory information was published in August. A potential high long-term risk to birds and mammals was identified.

A revised review report is under preparation.

v. Pyridaben

EFSA conclusion outstanding.

vi. Myclobutanil

A further revised review report was presented to the Committee based on the comments received pertaining to the need to amend the plant residues definition for monitoring. The definition for monitoring would remain as parent only.

A revised residue definition for risk assessment was still proposed to provisionally include the triazole metabolites to align with more recent conclusions for triazole substances (until an EU wide assessment had been completed).

Member States were asked to provide final comments by 6th January 2016, with the intention of noting the revised report in the January meeting.

vii. Thiamethoxam

The rapporteur Member State Spain circulated a reporting table concerning confirmatory data. However, it is not clear, whether the data submission was complete. This issue will be further explored with Spain.

viii. Metam (Review Report SANCO/13003/2011 Rev. 6 to be noted)

The assessment of the confirmatory data confirmed the outcome of the initial assessment. This was clarified in the revised review report which was taken note of by the Member States.

ix. Sulfuryl fluoride

The Commission presented the outcome of EFSA's technical report on the assessment of the confirmatory data and the commenting phase on them. The regulation for approval needs to be amended in order to take into account the confirmatory data submitted.

Member States were asked to provide their comments on the way forward by the 15th of January 2016.

x. Bromuconazole

The substance was introduced to the agenda for the first time. A brief history of the confirmatory data requirements was provided by the Commission as well as a summary of the outcome of the assessment by the RMS (Belgium) and peer review by EFSA and Member States. The data requirements had not been fully addressed and data gaps remain in relation to providing further information on residues of Triazole Derivative Metabolites (TDMs) in primary and rotational crops and products of animal origin.

However, the assessment of the RMS based on information available for levels of TDMs in wheat and using provisional reference values for the TDMs as agreed in 2007 at PRAPeR 14 toxicology meeting (Pesticide Risk Assessment Peer Review), indicated a high margin of safety from exposure to the triazole metabolites. Therefore, one possibility would be to allow continued approval with the applicant providing the further necessary data during product authorisation stage.

Member States were asked for their comments and positions by 6th January 2016. A revised review report would be prepared after further consideration of the file.

xi. Oxyfluorfen

The substance was introduced to the agenda for the first time. A brief history of the confirmatory data requirements was provided by the Commission as well as a summary of the outcome of the assessment by the RMS (Spain) and peer review by EFSA and Member States. An EFSA Conclusion in light of certain aspects of the confirmatory data was available. A critical area of concern for risk to aquatic organisms from parent and two metabolites was concluded. The Commission were considering the next steps and would prepare a revised review report with a proposal as soon as possible.

Member States were asked for comments by 15th January 2016.

xii Pyridaben

No discussion.

xiii. Sulfurylfluoride

No discussion

xiv. Tetraconazole

The Commission awaits feedback from RMS Italy on some points on which it needed clarification.

xv. Fluquinconazole

A mandate has been sent to EFSA. The outcome is expected end March 2016.

xvi. Metazachlor

The Commission inquired whether RMS United Kingdom already launched the new commenting round on elements that may clarify the dossier. It was explained that this procedure may be expected in January 2016.

xvii Prochloraz

A draft review report has been tabled. The main issue is the remaining ambiguities as regards the specification. EFSA suggests that at least an additional Ames test should be done with min level of prochloraz and max level of impurities.

Member States were asked to provide comments by 16 January 2016.

xviii 1-NAD

The Commission explained that ideally there should be a chronic study to address the risk to birds, instead of an extrapolation from acute data, or, alternatively, a residue study measured on foliage-dwelling arthropods. The Commission will adapt the review report and Member States were asked to provide comments by 16 January 2016.

xix. 1-NAA

The situation is identical to the above on 1-NAD.

Member States were asked to provide comments by 16 January 2016.

xx AOB

None.

A.05 Article 21 Reviews:

i. *Diflubenzuron*

The Commission informed Member States about the ongoing internal review at EFSA that was requested by the notifier. Greece informed the Committee about the receipt of data on Principal Component Analysis (PCA) and its intention to evaluate that data. The Commission reminded Member States that the submission of additional data is only possible upon request. Sweden outlined its position on the use of the Margin of Exposure approach.

ii. *Chlorpyrifos* – state of the dossier

Point postponed until the next meeting.

A.06 Amendment of the conditions of approval:

- *Fenazaquin* – information from the applicant

The applicant requested sharing some additional information with Member States. The information was uploaded on CIRCABC.

A.07 Basic substances:

1. Pilot projects: state of play

The Commission proposed to move forward despite the delay by Member States in presenting applications on previously identified substances, The intention is to internally identify possible candidates to be used in the pilot project, for this purpose a meeting of Working Group (WG) on basic substances will likely be organised in 2016.

2. New dossiers received:

i. Potassium sorbate

Member States were informed about the new dossiers received.

3. EFSA Technical Reports

None to report.

4. Draft Review Reports for discussion:

i. DAP

A draft Review Report has been prepared and presented. Comments were requested by 15th of January 2016.

ii. Sweet whey

A draft Review Report has been prepared and presented. Comments were requested by 15th of January 2016.

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

i. Draft Technical Guidance Document on the interpretation of points 3.6.3 to 3.6.5, and 3.8.2 of Annex II to 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) (for discussion)

The Commission thanked Member States for the discussion at the last PAFF committee and the written comments received after it.

The revised document was briefly summarised: in general, there are no fundamental changes to the previous version but some additions were added or some restructuration done with the aim to clarify. The environmental part of the document was deleted; however a clear commitment is given that a second GD focused on environment is intended to be developed. Some additional definitions (section 1.2) were deleted too in order to maintain the scope of the GD focused only on negligible exposure.

In addition to comments already raised by Member States via written form, one Member State commented that the application of the EFSA GD on Exposure may not have yet been applied in some dossiers currently under revision, and that for the Margin of Exposure approach (MoE) so far there is not much experience at Member State level. The Commission explained that it is because of that that a screening step is needed in addition to the MoE.

Member States were asked to provide any further comments in written format by 11 of January 2016. The corresponding expert WG was consulted in parallel with the same commenting deadline. It is the intention to vote on the GD at the PAFF meeting in March.

ii. Draft Guidance Document on Semiochemical Active Substances used in Plant Protection Products (SANTE/12815/2014 Rev. 4.1)

Cf. point A. 14.v.

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

No notifications submitted.

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

C50 WG (Belgium, rapporteur Member State United Kingdom)
Kinto (United Kingdom, rapporteur Member State Malta)
Proceed (United Kingdom, rapporteur Member State Slovenia)
Solar (Netherlands, rapporteur Member State Germany)

The Committee took note of the notifications submitted by Belgium, the Netherlands and the United Kingdom.

The Commission recalled that Article 36 defines very strict conditions for a refusal of mutual recognition. These include that the concerned Member State first must explore possible risk mitigation measures and shall not use this Article to challenge the decision of the rapporteur Member State concerning parts of the assessment which are not related to the risk to human or animal health or the environment.

For several of the notifications submitted by Member States serious doubts remain whether the provisions of article 36(3) were correctly applied and the Commission explicitly reserves its final position on these notifications.

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

Metalaxyl-M (Belgium)
Ethylene (Begium)
Fludioxonil (Belgium)
Prochloraz (Croatia)
Difenacoum (Finland)
1,3-Dichloropropene (France)
Chlorantraniliprone (France)
Profoxydim (France)
Spinetoram (France)
Spinosad (France)
Acetamiprid (Germany)
Chlorophacinone (Germany)
Epoxiconazole/Pyraclostrobin (Germany)
Lambda-cyhalothrin (Germany)
Lime sulphur (Germany)
Pyrethrins (Germany)
Glyphosate (Norway)
Quinoclamine (Norway)
Spirodiclofen (Norway)
1,3-Dichloropropene (Spain)
Chlorpyrifos (Spain)
Fosetyl-Aluminium (Spain)
Etephon (Spain)
Spirotetramat (Spain)
Gibberellic acid (Spain)
Lambda-cyhalothrin (Spain)

Pendimethalin (Spain)
Spinosad (Spain)
Tefluthrin (Spain)
Glyphosate (Sweden)
Pendimethalin (Sweden)
Pirimicarb (Sweden)

The Committee took note of the notifications submitted by Belgium, Croatia, Finland, France, Germany, Norway, Spain, and Sweden.

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

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

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

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

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

i. NAP (National Action Plans) Report
ii. State of play

The Commission updated on ongoing work. The Commission National Action Plan report is to be submitted to Parliament and Council during the Dutch Presidency.

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

EFSA expressed concerns regarding the quality of some renewal assessment reports (RAR), requesting the Member States to ensure that good quality dossiers are submitted; some contingency measures may be required for ensuring a proper and effective peer-review process. This concern will be also communicated to all risk assessment organisations in the Member States through the peer-review contact points.

EFSA confirmed the new approach for having general peer-review meetings for facilitating the exchange of views among experts from all Member States on risk assessment issues; the issues to discuss are those methodological risk assessment issues raised by the experts during the peer-review. The outcome will be published as EFSA Technical Reports. The report from the Ecotoxicology general meeting is under preparation. The next general meeting will be on mammalian toxicology in early 2016.

The procurement for creating a database of the list of endpoints, covering conclusions and reasoned opinions, is on-going. This database was discussed and its creation supported by the Pesticide Steering Network (PSN). It will facilitate in the future the work for Member States and EFSA, and will be publically available.

EFSA informed on the progress regarding the new draft assessment report (DAR) template including the report on harmonised classification (CLH-report) achieved at the PSN. As discussed in a trilateral meeting COM-EFSA-ECHA the RMS is requested to submit a proposal to ECHA on the harmonised classification even in cases where the current classification is supported. The submission should be done according to the alignment process, to ensure that both public consultations (on the RAR/DAR and on the CLH report) can be done in parallel and the RAC opinion is finalised before the deadline for the EFSA Conclusion.

A.14 Report from working groups:

i. Plant Protection Products (PPP) Application Management System (Authorisation database)

The Commission informed the Committee that there were two main activities ongoing; development and data migration.

A new release of PPPAMS (v 1.2) will be made available in February 2016. This new version improves a number of features and functionality of the system.

With regards to migration of national data, work is ongoing and progress is being made. Some of the data is being used in the ED Impact Assessment.

A meeting with the Implementation Steering Group (ISG) was scheduled for 14th December to present the updated PPPAMS and provide further details on the migration project.

The existing training manuals are being updated and made into web based manuals via the PPPAMS. Further training on PPPAMS will be organised for all MS sometime in 2016.

Work on the implementing act will be progressed in January and discussion will be arranged with the ISG (including industry) as necessary on the text.

ii. Low risk : presentation working document for proposal to review criteria

The Commission presented the background document for a proposal to amend the low risk criteria currently set in Regulation (EC) No 1107/2009. EFSA commented recently on it welcoming the separation between micro-organisms and chemicals but asking for further consistency in the environmental area.

The Commission intends to finalise the proposal as soon as possible. Member States may send final comments on the document by 15 January 2016 for a final discussion in the expert group. In parallel, the Commission is working on a roadmap concerning the proposal.

iii. Expert group on Article 43

The Commission informed the Standing Committee on the latest development on this guidance. Discussions involving the Commission, Member States and industries took place since the document was noted in July and allowed the identification of further guidance and slight amendments to the GD. The minutes of the meeting will be published and the Commission will upgrade the GD into a revised version.

iv. Post Approvals Issues group (PAI)

The Guidance Document on Article 43 was the main issue discussed. Cf. A 14.iii above.

v. Biopesticides

The working group on Biopesticides started to address the comments received on the draft guidance document on semiochemicals. Some issues are still open. On the side of micro-organisms, two high-priority points have been identified: drafting the RAR/DAR template for microorganisms and the issue for microorganism active substances approved as species to be renewed in the opposite of the common rule to approve such active substances at strain level.

vi. Seed treatment

The draft guidance document still needs some scientific inputs due to available recent data. In order not to postpone the publication of the guidance document, the GD might be proposed to be noted with the first sections drafted: legal clarifications, risk management issues, including harmonised risk mitigation and labelling provisions.

A.15 OECD

A first telephone conference of the OECD Expert Group on Novel Technologies and Their Use as Pesticides was held on the 5th of November. This expert group will initially deal with RNA interference (RNAi) based pesticides. During this first telephone conference, members were introduced, members presented their expectations of the group and there was a first discussion on the terms of reference.

A meeting will be held beginning of 2016. Member States will be updated regularly.

A.16 Bees:

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

The Commission recently mandated EFSA to review the risk assessment for seed treatment and granule applications, on the basis of the information submitted during the open call for data and new information available in the relevant scientific literature. EFSA was requested to carry out this task by end of October 2016.

In the mandate, EFSA was furthermore requested to liaise with Member States and producers in order to focus on uses relevant for the EU market.

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

Several Member States underlined the difficulties encountered at national level since the new guidance document on bees has not yet been noted.

EFSA informed additional information was requested from the applicants on residues on bee matrices in order to provide risk refinement options via real exposure.

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

Internal discussion ongoing; point postponed.

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

Applicants were requested to submit their comments concerning the conclusions. They were made available to Member States and will be further analysed.

5. Report - 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 2015, Bonn

The minutes of this workshop have been made available via CIRCABC.

Member States were requested to send suggestions for the next steps after this workshop, to the Commission by 15th of January 2016.

AOB

EFSA indicated that, during a meeting with ecotoxicology experts at the EFSA in September 2015, it was decided by the participants that the only option for the bee risk assessment is to use the new Guidance Document.

The Commission pointed out that the EFSA guidance document is not yet endorsed by the Committee and that EFSA shall perform a risk assessment in line with the provisions of the legislation. In the conclusion, EFSA shall in any case use the guidance which is applicable to the respective substance and highlight which part of the assessment is legally relevant for decision-making, in order to avoid confusion.

A.17 Court cases:

No new cases.

A.18 Endocrine disruptors:

- Impact assessment

The Commission updated on the state of play of the impact assessment. On 6th November 2015, the Commission organized a technical meeting where the Joint Research Centre (JRC) presented to interested parties the methodology developed to screen about 600 chemicals for estimating which substances would be identified as endocrine disruptors according to the options described in the roadmap. On 10 December 2015, the list of chemicals to be screened was uploaded on the Directorate General for Health and Food Safety (SANTE) website together with the rationale. The screening of all substances is expected to be finalised by end of April 2016 and the impact assessment completed by end of 2016. Once the screening is finalized, its results will be published together with the methodology. The decision making concerning the criteria for identifying Endocrine Disruptors will follow thereafter and will be taken by the College of the Commission.

A.19 Minor Uses:

- State of play

A presentation to introduce the Coordination Facility was given at the Standing Committee on Plants, Animals, Food and Feed in October. At this meeting the coordinator gave an update on the activities of the Minor Uses Coordination Facility. Early November the minor uses website has been launched (www.minoruses.eu). The Interim Narrative Report of the Coordination Facility (covering the period 15 April 2015 – 15 November 2015) has been prepared. This report provides an overview of the activities of the Coordination Facility in the first 7 months and an indication about the level of achievement of the objectives as laid down in the grant agreement.

A.20 Interpretation issues:

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

- Clayed charcoal

It was proposed to consider the intended use for this product to fall within the scope of Regulation (EC) 1107/2009. Member States could oppose until the 16th of December 2015.

2. Questions and answers

No updates.

A.21 Classifications under Regulation (EC) No 1272/2008:

1. Status of harmonised classifications
2. Implementation of the criteria in Annex II points 3.6.2 to 3.6.5 to Regulation (EC) No 1107/2009

No Discussion.

A.22 Glyphosate:

- State of the dossier

See Agenda item A.03.03.03.

A.23 Exchange of information from the section Pesticide Residues 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 Changes of toxicological endpoints and consequent review of authorisations.

Discussion postponed.

A.25 New greenhouse operator exposure model.

Discussion postponed.

A.26 Guidance Document DegT50 (SANCO/12117/2014 - final, 12 December 2014) – Clarification on implementation (DE).

Germany informed of the difficulties expressed by Member States in implementing this Guidance Document within the set deadlines (i.e. 1.5.2015). Germany outlined three alternatives and will explore further. The Commission thanked Germany for this welcome initiative but recalls that the date had been chosen as to ensure consistency with the GD Focus Groundwater II which had to be implemented at the same date.

A.27 Feedback from the workshop on harmonisation of toxicological risk assessment for micro-organisms – CTGB, 12 and 13 November 2015.

The Commission informed the Committee about the main topics discussed in this workshop. Some further action points were identified which will be forwarded to the Working Group on Biopesticides.

A.28 Feedback from the International Conference on Chemicals Management, Fourth session (ICCM4), Sept/Oct 2015 (ENV).

Postponed.

A.29 Way ahead on identification of inacceptable co-formulants (Article 27).

The Commission informed the Committee about the forthcoming discussion on the identification of unacceptable co-formulants and asked Member States to nominate experts (risk assessors and/or managers) and show their interest in participating by the 16th of December 2015.

A.30 Reference specification for Straight Chain Lepidopteran Pheromones (SCLP) blend (E,E/Z)-7,9-dodecadienyl acetate (= blend (E,Z)-7,9-dodecadien-1-yl acetate + (E,E)-7,9-dodecadien-1-yl acetate) (DE)

Postponed.

A.31 Tefluthrin - Article 56 submission by Syngenta (DE).

Postponed.

A.32 Phosphonic acid (inorganic metabolite) - Assessment of relevance (DE).

Postponed.

A.33 Acetamiprid (new toxicological reference values) (DE).

Discussions took place on whether there is a need to amend the existing toxicological reference values in view of the recommendations made by EFSA in the framework of the Scientific Opinion on the developmental neurotoxicity potential of acetamiprid and imidacloprid.

Member States were asked to submit their positions by 8 January 2016.

A.34 Straight Chain Lepidopteran Pheromones (SCLP) : new compound amended Review Report (SANCO/2633/08 Rev. 9) (to take note)

This point was added to the original agenda.

The note taking was postponed at the request of one Member State.

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 3-decen-2-one, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. (Draft Review Report Doc. SANTE/10447/2015 Rev. 0)

Two Member States voted against because they considered that enough information was available (including a new study) to confirm that the substance is not genotoxic and that it could be exempt from setting of MRLs.

Three Member States abstained because they considered that approval could be supported by requesting a Comet Assay to be submitted as confirmatory information.

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 metsulfuron-methyl, 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/10319/2015 Rev. 2)

Two Member States abstained as they considered that a request for confirmatory information in relation to the residues definition should be requested.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance benzovindiflupyr 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 Implementing Regulation (EU) No 540/2011. (Draft Review Report Doc. SANTE/11259/2015 Rev. 1)

One Member State voted against because the specification was not finalised.

One Member State voted against because no confirmatory requirement was set to further investigate endocrine disrupting potential.

One Member State abstained as they had not yet reached a final position.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance pyraflufen-ethyl 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/10805/2015 Rev. 1)

One Member State voted against because they believed further genotoxicity studies were required for one impurity in the technical material.

One Member State abstained because they believed that confirmatory information should be requested to confirm the compliance of the technical specification with the material used in the (eco)toxicity studies.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest.

The draft document was presented for vote. No particular comments were raised.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance lambda cyhalothrin 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 Implementing Regulation (EU) No 540/2011. (Draft Review Report Doc. SANCO/12282/2014 Rev. 3)

One Member State voted against because they believed the approval should be restricted to indoor uses given the outcome of the risk assessment.

One Member State voted against and three Member States abstained because of the possible risks for workers, aquatic organisms, wild mammals and non-target arthropods identified for the representative uses.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation withdrawing the approval of the active substance Z,Z,Z,Z-7,13,16,19-docosatetraen-1-yl isobutyrate, 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.

The draft document was presented for vote. No particular comments were raised.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation withdrawing the approval of the active substance Z-13-hexadecen-11-yn-1-yl acetate, 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.

The draft document was presented for vote. No particular comments were raised.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance iprovalicarb 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/11968/2015 Rev. 1)

One Member State voted against due to the potential for groundwater contamination in low-clay containing soils.

One Member State voted against as they wanted a requirement to provide confirmatory information in relation to endocrine disrupting potential.

Vote taken: Favourable opinion.

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

FVO presented results of audit series and outcomes of a formulation laboratories workshop held in September in Grange. In addition, a presentation was given on the results of an analysis concerning reports submitted by Member States under Article 68. To follow up on the outcomes presented by FVO, the Commission proposed to the PAFF to organise two specific working group: one in April 2016 focused on enforcement matter with the first task to elaborate a proposal for a template for reporting under Article 68 and one WG later in September on formulation laboratories issues. For the WG on enforcement the Commission asked Member States to nominate a delegate by 15 January 2016. Some Member States already expressed their support to the initiative.

M.02 New scientific publications

Nothing to report.

M.03 AOB

None.

M.04 Date of the next meeting

The next meeting was confirmed for 28-29 January 2016.