EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

sante.ddg2.g.5(2017)3980920

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 17 MAY 2017 - 18 MAY 2017

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/6f979946-8b46-4b33-b9ae-0a6f34cafb36*

A.01 Summary Report of previous meetings.

The summary report of the meeting on 30 March will be published at a later stage.

A.02 New active substances:

1. New admissible dossiers to be noted:

No new dossiers

2. Exchange of view on new European Food Safety Authority (EFSA) conclusions

No specific conclusions identified

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

i. Beta-cypermethrin

Member States were updated on the timeline for decision making; importantly they were informed that a Technical Barriers to Trade (TBT) notification was ongoing. Comments from India had already been received and were being responded to by the Commission.

The proposal for non-approval would be added to the agenda for possible vote at the July Committee meeting. Some further comments from the applicant had been received and been made available to Member States through CIRCABC. Final positions were invited by 7 June.

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play.

No news.

2. Exchange of view on EFSA conclusions:

i. Thiram

Member States were informed that the Commission had met with the Thiram Task Force on 16th May to discuss the file. Member States were informed that a position paper had been sent by the applicant and was available on CIRCABC. A summary of the comments received since the March meeting was provided and Member States were informed that the Commission was now considering whether any form of approval was possible given the issues identified particularly the risk to birds and mammals. Member States were invited to submit further comments and views by 7 June. A renewal report and draft Regulation would be made available before the July Standing Committee on Plants, Animals, Food and Feed (PAFF Committee).

ii. Propineb

The Commission presented the EFSA Conclusion and some of the severe concerns identified, including lack of consumer risk assessment due to major data gaps and endocrine disrupting properties of major metabolite PTU. Member States were asked to reflect on the issues presented and provide their initial views by 16 June 2017.

iii. Oxasulfuron

The Commission presented the EFSA Conclusion and some of the key concerns identified, including a great number of data gaps, deficiencies in some of the submitted studies and the resulting non-finalised environmental and consumer risk assessment. Member States were asked to reflect on the issues presented and provide their initial views by 16 June 2017.

iv. Bifenazate

The Commission presented the EFSA Conclusion and some of the key concerns identified, including a great number of data gaps, deficiencies in some of the submitted studies and the resulting non-finalised environmental and consumer risk assessment. Member States were asked to reflect on the issues presented and provide their initial views by 16 June 2017.

3. Draft Review/Renewal Reports and Regulations for discussion:

i. Maleic hydrazide

The Commission presented a draft Regulation proposing renewal of approval of the substance with reduced level of impurity hydrazine. The Commission intends to submit the proposal for renewal of approval for vote in July. Member States were invited to send in their final comments by 7 June 2017.

ii. 2,4-DB

The Commission referred back to the draft Regulation proposing renewal and the renewal report presented in March 2017 which have not been subject to modifications. No specific comments have been raised by Member States by the deadline of 21 April either. It seems therefore that the approach is generally supported and the interservice consultation will be launched for a possible vote in July 2017.

iii. Carfentrazone-ethyl

The Commission referred back to the draft Regulation proposing renewal and the renewal report presented in March 2017 which has not been subject to modifications, with the exception of some editorial corrections. No specific comments have been raised by Member States by the deadline of 21 April either, although some Member States already indicated their reservations. It is intended to launch the inter-service consultation for a possible vote in July 2017.

iv. Acetamiprid (no discussion – only short information to Member States)

Comments received by Member States have been uploaded to CIRCABC. New versions of the documents will be uploaded as soon as possible. Member States were invited to send in their comments by 7 June 2017.

v. Silthiofam

Comments received by Member States have been uploaded to CIRCABC. Proposal currently under discussion due to need for confirmatory information on potential relevance of groundwater metabolites linked to proposal for classification of parent compound.

vi. Isoxaflutole

Member States were informed that since the March meeting several Member States had submitted comments indicating that they could not support renewal under the conditions of negligible exposure given that there is no EU agreed guidance in this area. The Commission informed Member States that the draft report concerning Article 4.7 (need for isoxaflutole to control a serious danger to plant health) was available and that, once finalised, this would be explored. Member States were asked for comments.

vii. Imazamox

The Commission intends to submit the proposal for renewal of approval for vote in July. Member States were invited to send in their final comments by 7 June 2017.

viii. Pseudomonas chlororaphis strain MA342

The Commission presented the EFSA Conclusion and some of the key issues identified, in particular in relation to uncertainty over the consumer exposure to

genotoxic metabolite DDR. Member States were asked to reflect on these concerns and provide their comments.

ix. Iprodione

A draft Renewal Report and draft Regulation were uploaded on CIRCABC. A large number of concerns were identified by EFSA, which are reflected in the documents. Member States were asked to reflect on these concerns and invited to send in their comments by 7 June 2017.

x. Flupyrsulfuron-methyl

No discussion took place but Member States were reminded that the proposal for non-renewal of approval was now undergoing a TBT notification. Member States were also advised that the proposal for non-renewal of approval would be added to the agenda for possible vote at the July Committee. Final positions were invited by 7 June.

4. AOB

i. Corrigendum as regards information on purity in the Annex to the Regulation renewing the approval of Coniothyrium minitans strain CON/M/91-08.

For this active substance, an incorrect minimum purity is stated. The Commission informed that Corrigendum will be prepared after adoption of the Regulation renewing the approval of Coniothyrium minitans CON/M/91-08. The Review Report, which will be published soon will already contain the correct amount.

A.04 Confirmatory Data:

1. Bifenthrin

Several Member States expressed their concern as regards the potential for recolonization of non-target arthropods in-field and the reliability of the information submitted as regards the potential of the compound for bioaccumulation and biomagnification. As it seems difficult to realistically mitigate the risks, there is support to further restrict the use of the substance and a limitation to greenhouse use only seems the most appropriate alternative. It is intended to launch the interservice consultation in this sense for a vote which will not take place before autumn, given the need to notify the measure to WTO via the TBT procedure.

2. Thiamethoxam
3. Clothianidin
4. Imidacloprid

Points A 04.2-4 were discussed together.

The Commission informed the Standing Committee of the ongoing procedures for the three proposals and indicated that the proposals will not be included for an opinion in the July PAFF Committee.

The Commission informed the Standing Committee of comments received from many stakeholders.

Feedback from Member States was made available on CIRCABC.

The Member States which had not sent comment in so far were invited to do so by 16 June 2017.

The Commission informed the Committee of a survey executed by JRC and informed it is organising a presentation of this survey in the next meeting.

One Member State, supported by 2 Member States, inquired on the Bee Guidance Document and the need for an expert meeting on this topic

5. Tetraconazole

The Commission referred back to the draft Review Report tabled in March and which remained unchanged, with the exception of some minor editorial corrections. As it seems that the remaining issues have been satisfactorily addressed it is proposed to submit this report for note-taking in July 2017.

6. Cyflumetofen

The Commission informed the Standing Committee of its intention of addressing the unresolved concerns from the confirmatory data by restricting the conditions of approval. Member States were invited to comment on the Commission proposal. The draft restriction act may be proposed for vote in the October PAFF Committee.

7. Napropamide

The Commission refers back to the draft Review Report tabled in March and which remained unchanged. Most of the commenting Member States agreed that the remaining issues have been satisfactorily addressed or can be adequately mitigated. It is therefore proposed to submit this report for note-taking in July 2017.

8. Malathion

Several Member States expressed their concern, in particular, as regards the high risk to birds. As it is realistically problematic to mitigate such risk, there is a support to further restrict the use of the substance and a limitation to greenhouse use only seems the most appropriate alternative. It is intended to launch the inter-service consultation in this sense for a vote which will not take place before autumn, given the need to notify the measure to WTO.

10. Quinmerac (revised Review Report to be noted)

The Committee took note of the revised Review Report (SANCO/12192/2010 Rev. 1).

11. Dithianon

Comments received by Member States and the applicant have been uploaded to CIRCABC. The Commission is still reflecting on the possible options. Member States were invited to send in their comments by 7 June 2017.

12. Tri-allate

The dossier is being studied by the Commission. One problem relates to the fate and behaviour of the metabolite DIPA, its toxicity and its relevance for groundwater. Also primary plant metabolism and the setting of a residue definition for monitoring and risk assessment may need further attention. The potential for biomagnification in the aquatic food chain, the risk to fish-eating mammals and earthworms seems well addressed or can be sufficiently mitigated.

13. Eugenol

The EFSA Technical Report has been received and is further studied by the Commission. The dossier intimately linked to those for geraniol and thymol, as they are placed on the market as a mixture of the three and defended by the same notifier. One problem relates to the impact of methyleugenol, a naturally occurring genotoxic carcinogen and component of many natural essential oils. Furthermore, shortcomings have been identified as regard the comparison between the natural background exposure and the uses as Plant Protection Products (PPP), in the field of human exposure, birds and aquatic organisms.

14. Geraniol

See sub-point. 13 "Eugenol" above.

15. Thymol

See sub-point 13 "Eugenol" above.

16. Triazole Derivative Metabolites (TDM)

The EFSA Technical Report has been received in August 2016 and relates to a large series of compounds of the triazole family. The Commission is currently drafting a mandate to EFSA which would focus on toxicity of the different metabolites, their residues and effects on consumer exposure, possibly in a phased approach.

A.05 Article 21 Reviews.

No news.

A.06 Amendment of the conditions of approval:

1. New admissible dossiers to be noted:

No new dossiers

2. Metam

The Commission brought to the attention of Member States the finalisation of additional information submitted by the applicant to support a possible change of the acceptable operator exposure level (AOEL) for the metabolite MITC. The rapporteur Member State after having evaluated data and coordinated due peer review among Member States, concluded that that set AOEL is confirmed and no change is admissible on the basis of the new submitted data. Hence, the assessment is recorded as concluded.

A.07 Basic substances:

1. Pilot projects: state of play

2. New dossiers received (only for information):

i. Flavan-gallo tannins
ii. Grape cane tannins

The Commission informed Member States of the received applications and noted that the name for the flavan-gallo tannins was changed to Castanea and Schinopsis sp tannins.

3. Exchange of views on EFSA Technical Reports - (no specific report identified)

No discussion took place.

4. Draft Review Reports for discussion:

i. Equisetum (extension of use)

The Commission brought the attention of Member States to a revised Review Report which would support extension of use on potato and strawberries as data submitted demonstrate comparability to other uses initially approved as safe.

A.08 Exchange of views on Guidance Documents.

There were no documents available.

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

32 notifications were submitted concerning glyphosate from the Netherlands. One notification was submitted concerning tebufenpyrad.

The Committee took note of the 33 notifications.

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

No notification was presented for note-taking to the Committee.

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

Lime sulphur (calcium polysulphid) (Belgium)
Spinetoram (Belgium)
Penoxsulam (Belgium)
Spirotetramat (Belgium)
Metam (incl. -potassium and -sodium) (Belgium)
Flonicamid (IKI-220) (Belgium)
Cyantraniliprole (Belgium)
Quizalofop-P-ethyl (Finland)
Clomazone (Finland)
Alpha-Cypermethrin (aka alphamethrin) (Greece)
Propanil (Greece)
Quinclorac (Greece)
(Z)-11-Tetradecen-1-yl acetate, (Z)-9-Tetradecen-1-yl acetate (Greece)
Beta-Cyfluthrin, Clothianidin (Hungary)
Fludioxonil, Metalaxyl-M, Thiamethoxam (Hungary)
Boscalid (formerly nicobifen), Pyraclostrobin (Hungary)
Epoxiconazole, Pyraclostrobin (Hungary)
Abamectin (aka avermectin) (Ireland)
Fluopyram (Ireland)
Isoxaben (Latvia)
Triflusulfuron (Latvia)
Propyzamide (Latvia)
Carbetamide (Latvia)
Bromoxynil (Latvia)
Fludioxonil (Lithuania)
Trichoderma atroviride strain SC1 (Luxembourg)
Plant oils/ Rape seed oil, Pyrethrins (Luxembourg)
Lime sulphur (calcium polysulphid) (Luxembourg)
Bacillus thuringiensis subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348 (Poland)
Oxadiazon (Portugal)
Propanil (Portugal)
1,3-Dichloropropene (Portugal)
Clomazone, Pendimethalin (Portugal)
1-Naphthylacetic acid (1-NAA), 6-Benzyladenine (Portugal)
Spinosad (Portugal)
Clothianidin (Portugal)
Thiamethoxam (Romania)

Imidacloprid (Romania)
Clothianidin (Romania)
Cypermethrin (Romania)
Potassium hydrogen carbonate (Slovakia)
Imazamox, Pendimethalin (Slovakia)
Propaquizafop (Slovakia)
Azadirachtin (Slovakia)
Fatty acids C7-C18 and C18 unsaturated potassium salts (CAS 67701-09-1) (Slovakia)
Aureobasidium pullulans (strains DSM 14940 and DSM 14941) (Slovakia)
Copper hydroxide (Slovakia)
Trichoderma harzianum strains T-22 and ITEM 908 (Slovakia)
Plant oils/ Rape seed oil, Pyrethrins (Slovakia)
Bifenthrin (Slovakia)
Lime sulphur (calcium polysulphid) (Slovakia)
Spinosad (Spain)
Oxamyl (Spain)
Cyantraniliprole (Spain)
Potassium hydrogen carbonate (Sweden)

The Committee took note of the notifications submitted by Belgium, Finland, Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Poland, Portugal, Romania, Slovakia, 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.

The Commission requested Member States to ensure to enter all information requested into the Plant Protection Application Management System, as this information is necessary to judge whether any such authorisation was granted according to the provisions of Article 53 of Regulation (EC) No 1107/2009.

In case of doubt, the Commission, in line with the provisions of Article 53(2), will consider asking EFSA to evaluate whether the preconditions for granting an authorisation according to Article 53 are fulfilled.

A.12 News from European Food Safety Authority (EFSA).

EFSA gave an update on the following points:

- Open points from previous meetings
- Update on Pesticide Steering Network (PSN) and Action Plan
- Update on Endochrine Disruptors guidance consultation plan
- New Member States' requests
- Other issues related to the peer-review process
- Plant Protection Products and their Residues (PPR) Panel plenary this week
- Update on glyphosate public access to documents (PAD) requests and related issues.

A.13 News from the Directorate General for Health and Food Safety (SANTE) Directorate F, Health and Food Audits and Analysis (former FVO).

No presentation was given.

A.14 Report from working groups:

1. Plant Protection Products Application Management System (PPPAMS)

No news.

2. Post Approvals Issues group (PAI) (reminder on zonal applications)

The Member States were reminded to inform as swiftly as possible the applicants for Article 43 applications about the allocated zonal rapporteur Member States, in order not to delay nor undermine the process of renewing product authorisations.

3. Sustainable plant protection experts group Dutch proposal

The Commission informed Member States on the outcome of the last meeting on 4-5 April, which included a workshop discussing Member State proposals to increase the availability of low-risk products and that would require amendment of Regulation (EC) No 1107/2009. Also discussed was the reporting table to collect information on the progress of Member States in implementing the implementation plan on low-risk products and Integrated Pest Management (IPM). Member States will be sent a request for information before the summer. Member States were also requested to send in information on their nominated experts for the upcoming meeting of the Working Group (WG) on low-risk substances/products that will reconvene on 28 June.

4. Working group on Biopesticides

No meeting.

5. Working group on Seed Treatments

No meeting.

6. Working Group on implementation of Ruling in C-442/14

No news

7. Working Group on Co-Formulants

The Standing Committee was informed that this WG will reconvene to discuss the way forward on co-formulants. The WG will discuss the draft regulation setting criteria and a work program to identify the unacceptable co-formulants as well as the first regulation populating Annex III with identified unacceptable co-formulants.

8. Working Group on the implementation of the Sustainable Use Directive

The first meeting in Grange will be held on 31 May 2017. During the meeting, also the topic of statistics in pesticides will be discussed. To this end, DG ESTAT will be present on the spot. Member States are requested to assure that the participants of the meeting are fully briefed in that respect.

A.15 OECD

The Standing Committee was reminded that OECD will hold a series of meetings related to pesticides in Paris in June 2017. Member States were invited to report to the Commission their intention to take part in the Working Group on Pesticides (WGP). The Commission will organise a teleconference to coordinate the EU position in the view of the WGP.

A.16 Court cases.

No new developments.

A.17 Endocrine disruptors.

No new developments since the last discussion.

A.18 Minor Uses.

The following update was provided to the Standing Committee by the Coordinator of the European Minor Uses Coordination Facility (EUMUCF)

- From 28-30 March 2017, a series of meetings of the Minor Uses Expert Groups were organised in Brussels. The meetings were attended by more than 120 people from more than 20 Member States. Two plenary sessions were

organised: feedback questionnaire "overview Minor Uses work in MSs" on how the minor uses work is organised in the different Member States and a plenary session on the REFIT of Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005. This was followed by discussions in Breakout Groups to gather input for the REFIT process.

- The EU Minor Uses database EUMUDA is an important tool to collect the minor use needs from Member States and to manage all projects with the aim to find chemical or non-chemical solutions for minor uses gaps. The MUCF is in the process to develop a new EUMUDA.
- It is now possible to subscribe to the minor uses newsletter.

A.19 Interpretation issues:

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

i. Plant strenghteners (request by Lithuania)

Discussion postponed.

2. Questions and answers

No new questions or answers.

A.20 Classifications under Regulation (EC) No 1272/2008 / REACH:

1. Status of harmonised classifications

An updated table was made available on CIRCABC.

2. Preparation of Harmonised Classification and Labelling dossiers (CLH dossiers) by Member States

The Commission presented a preliminary draft of an Implementing Regulation amending Regulation (EU) No 844/2012 on the renewal procedure. The draft proposes to make mandatory the submission by Member States of a harmonised classification dossier to the European Chemicals Agency (ECHA) in parallel to the submission of the draft Renewal Report.

One Member State indicated that there were issues with existing harmonised classifications which were adopted under Directive 67/548/EEC and it would be interesting if there would be an obligation to update such classifications.

One Member State indicated that the provisions concerning the transition are important and sufficient time should be provided for Member States to comply with the new requirement. It also indicated that the new merged template CLH and DAR should be made available as soon as possible to Member States.

One Member State indicated that it welcomed the initiative by the Commission and that it was already using the new merged template.

EFSA confirmed that in the case where Member States would submit a proposal for harmonised classification at the same time as the DAR, ECHA and EFSA were committed to align the assessment procedures. The 2 agencies are committed to cooperate and avoid duplication of work. EFSA strongly recommended Member States to use the new merged template in all cases and consider submitting a proposal for harmonised classification for all substances even to confirm a existing classification, unless there is already a recent Risk Assessment Committee (RAC) opinion that has considered all available studies.

3. Report from the Working Group (WG) on Assessment Reports (AR template) (merging CLH and xAR templates)

The Standing Committee was informed by the Commission and EFSA that the merged template containing both information regarding risk assessment and proposed classification is finalised. The Guidance on how to submit this document and how to submit dossiers to both EFSA and ECHA still needs to be fine-tuned. Member States will be asked to take note of the merged template in July. They can already use the finalised guidance to ease the processing by both EFSA and ECHA.

A.21 Glyphosate:

• State of the dossier

The Commission updated the Committee on the ongoing state of play and key developments.

The Commission informed the Committee that on 15 March 2017 the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) had agreed, by consensus, that glyphosate should not be classified as carcinogenic, nor mutagenic or toxic for reproduction. Member States were informed that the final Opinion was expected to be received in June and that the date or receipt would be published in the Official Journal of the EU, as foreseen by Commission Implementing Regulation (EU) No 2016/1056.

Member States were informed that Commissioner Andriukaitis had informed the College on 16 May on the way forward concerning glyphosate. The College agreed that the Commission services should restart the discussions with Member States about the possible renewal of approval of glyphosate for 10 years. Member States were advised that discussions on a proposal would begin at the July Committee meeting, with a possible vote after the summer break.

Member States were advised that the Commission was taking into account the latest state of scientific research and in particular the conclusion by the European Chemical Agency's (ECHA) Risk Assessment Committee (RAC) and that the conclusion on the ongoing mandate on potential endocrine activity of glyphosate would also be taken into account in the proposal.

Some Member States questioned the proposed approval period of 10 years rather than the standard 15 years. The Commission explained that 15 years is the maximum period for renewal foreseen in the legislation but that glyphosate is not a routine case given that it is probably the most widely used substance in the world. While the Commission has no reason to doubt the safety of the substance, it acknowledges the public sensitivity and debate regarding its overall use.

This is why the Commission will propose to the Member States 10 years as a starting point for debate.

With regards to the so called 'Monsanto Papers' the Commission explained that this matter was taken seriously and that given the thorough scrutiny of all available information by the two EU agencies, there are no grounds to call into question the scientific assessments and conclusions on glyphosate carried out in the European Union. Member States were informed that President Juncker had replied to a letter sent by 29 MEPs on the matter. Belgium had raised this issue ahead of the meeting – the correspondence was shared with all Member States via CIRCABC.

The Commission reminded the Committee about the European Citizens' Initiative for which the process to collect statements of support remained ongoing.

Finally, Member States were informed that a Paper by José Tarazona et al. had recently been published in the journal Archives of Toxicology entitled 'Glyphosate toxicity and carcinogenicity: a review of the scientific basis of the European Union assessment and its differences with IARC'.

A.22 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations (no new meeting has taken place since March 2017).

No news as no meeting has taken place in the meantime.

A.23 Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).

The Commission informed the Standing Committee that the process to select the contractor who should perform the independent external study is ongoing. The study is expected to commence very soon and will run for one year.

A dedicated website has been created for the evaluation: http://ec.europa.eu/food/plant/pesticides/refit_en. The website contains general information regarding the evaluation, the consultations foreseen, the timeline, the Roadmap as well as feedback received on the Roadmap.

In the framework of the evaluation a comprehensive consultation of all relevant stakeholders will be conducted. Member States will be consulted via an online survey, followed with in-depth interviews as well as focus groups. Four focus groups are foreseen covering i. the risk assessment process, ii. the risk management and decision

making process, iii. the MRL setting process, and iv. the PPP authorisation process. EFSA will also be invited to be part of the focus groups as well as consulted via in-depth interviews.

The Commission stressed the importance of participation by all Member State Competent Authorities in the online survey and will inform the Standing Committee when the survey will be launched. The Commission then concluded by informing about other consultations foreseen for the evaluation: an open public consultation being open for three months during the fall of 2017 with the aim to collect the views from citizens and consumers, a survey targeting stakeholders, and a survey specifically targeting Small and Medium Enterprises.

A.24 Exposure of florists to plant protection products from cutflowers (follow-up from March meeting).

The Commission gave an overview of the feedback received from 3 Member States and asked for further comments by 16 June 2017.

A.25 New rules on availability of draft documents for discussion.

The Commission clarified some new rules concerning the making available of draft documents ahead of meetings of the Standing Committee. These rules do not reflect a fundamental change of policy but should be seen as a clarifying the existing policy concerning the status of draft Commission documents within the different steps of internal consultation.

In the future, only those drafts which underwent a complete Interservice Consultation will be made available as draft Commission documents (e.g. draft Commission Implementing Regulation). Draft documents at an earlier stage may still be shared with the Committee, but they will no longer be considered as Commission drafts. In order to avoid confusion between the two categories of documents, the early drafts will be provided in a different format, without any reference to the Commission (i.e. no headers) and bearing a clear disclaimer that they must not be regarded as Commission draft documents.

The objective of the disclaimer is to be very clear about the preparatory nature of the document and to ensure that the document is presented in such a way that it cannot be confused with an act or draft act endorsed or adopted by the Commissioner's College. The disclaimer is not meant to change the Commission practice to consult with Member States, neither is it meant to impact or restrict the possibility for Member States to carry out their preparatory work. Also in that work the disclaimer will help to be clear about the nature of the document.

The disclaimer states that the document 'may contain confidential and/or privileged material' . If that was the case for a specific draft act general rules on classification of documents would in any case have to be followed.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance propoxycarbazone 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 Renewal Report SANTE/11954/2016 Rev. 1).

One Member State voted against because of metabolites leaching in groundwater and risks to aquatic organisms. One Member State abstained because of metabolites leaching in groundwater.

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 benzoic acid 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 Renewal Report SANTE/10147/2017 Rev 1).

The draft Regulation was presented 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 pendimethalin, 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 SANTE/11656/2016).

One Member State voted against for persistent, bioaccumulative and toxic (PBT) criteria. One Member State abstained because of risk to aquatic organisms. One Member State abstained because they considered there is a need to review the potential for endocrine disruption. Two Member States abstained for ecotoxicity.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance picoxystrobin, 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 Renewal Report SANTE/11601/2016 Rev. 2).

One Member State voted against as they considered that the genotox assessment should be finalised before a final decision is taken. Nine Member States abstained as in general they considered that, whilst there were many concerns identified in the EFSA Conclusion, these could be dealt with via confirmatory information or at national level during renewal of authorisation.

One Member State who supported the proposal made it clear that they did not support the approach of not setting any reference values when the genotoxic potential could not be concluded. However, they acknowledged that this issue aside, there are many issues identified and therefore that overall, the proposal is supported.

This item will be referred to the Appeal Committee according to the relevant procedures.

Vote taken: No opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance propyzamide, 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 11797/2016 Rev. 1).

Vote was postponed due to ongoing inter-service consultation. The Commission brought to the attention of Member States the new draft which has been amended to delete any requirement for confirmatory data. Several Member States expressed their potential support of the proposal, however it was underlined the need to have the assessment of relevant confirmatory information at European level to avoid potential disharmonised assessments. The Commission will further reflect on the issue. Two Member States expressed their position against the proposal due to potential groundwater pollution and missing information on residues metabolites.

Vote postponed

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation withdrawing the approval of the active substance repellents by smell of animal or plant origin/tall oil pitch, 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANCO/2632/08 Rev. 5).

The draft Regulation was presented for vote.

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 repellents by smell of animal or plant origin/tall oil crude, 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANCO/2631/08 Rev. 5).

The draft Regulation was presented for vote.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties.

The Commission reminded that after the last discussion of this PAFF Committee on criteria to identify endocrine disruptors (EDs) on 28 February 2017, a meeting on the ED-criteria took place on 7 April 2017 with the Member States Competent Authorities for biocidal products. This meeting focused on the growth regulators provision, which had been already agreed in the PAFF Committee.

After a discussion on the way forward concerning EDs in the College on 16 May, the Commission has now decided to progress first on the legal act for plant protection products.

The Commission recalled that a revised text for the criteria on plant protection products had been uploaded on CIRCABC two weeks before the meeting. The Commission presented the changes introduced in the last revised version of the criteria. The main changes with respect to the draft discussed on 28 February are:

1) in recital 4, it is clarified that the criteria identify known and presumed EDs with respect to human health;
2) in recital 7, the provision on growth regulators (GR) is better explained;
3) in the annex, the provision on biological plausibility is redrafted and given more prominence in the text;
4) in the annex, the provision on growth regulators is unchanged, except for one sentence which has been moved to the corresponding recital.

The Commission presented few additional minor clarifications introduced to the text uploaded in CIRCABC in the last few days. A paper copy was distributed to the Member States delegates and the corresponding file uploaded on CIRCABC. The changes are:

1) in recital 4, it is explained in clearer terms that this recital is only relevant for human health;
2) in recital 7, it is specified why growth regulators are not expected to pose a risk to vertebrates and that even organisms of the same phylum of the target organisms will be subject to a risk assessment.

Three Member States asked the Commission to clarify when the text on the amendment to point 3.6.5 of Annex II of Regulation (EC) No 1107/2009 will be tabled.

One Member State asked to clarify which guidelines are referred to in the revised provision on biological plausibility. The same Member State asked whether the provision on growth regulators could specify that ED properties for invertebrates will be sufficiently assessed in the risk assessment. In their view, this would be necessary because current data requirements do not specify this enough. In order to do so, this Member States suggested inserting in the text that "particular attention should be paid to the ED properties of GR in non-target invertebrates". A revised text was agreed upon addressing this comment.

One Member State asked whether the words "unacceptable effect" in recital 7 should rather read "unacceptable risk". The Commission clarified that the wording comes from Regulation (EC) No 1107/2009.

One Member State indicated that they appreciate the modification in recital 4 to clarify that this recital only applies to human health. They would suggest a different wording, but they can accept the wording proposed by the Commission, since it is equivalent in meaning. This Member State also indicated that they would like to see, in the approval regulation of each GR approved, a recital which transparently acknowledges that the substance can be approved as growth regulator and under consideration of the provision on GR of the ED criteria.

The Commission reassured that it is standard procedure to clarify in the recitals in the approval regulations for single substances the specific conditions allowing their approval; in the case of substances with intended mode of action as GR, it would be appropriate to mention – if applicable - that the substance falls under the provision of the ED criteria specific for GR.

One Member State thanked the Commission for having made all efforts to accommodate as much as possible the comments coming from different Member States and encouraged all Member States to consider this fact. This Member State indicated that they wish all Member States will implement the criteria in a harmonized way. In order to do so, they urge the Commission to make sure that the agencies finalize the guidance document (GD) in time for when the criteria are adopted. This Member State also stressed it is in favour of the amendment to point 3.6.5 and would like to resume discussions on it.

One Member State thanked the Commission for all the efforts done to accommodate comments on the criteria. Regarding recital 4, they agree with the clarification that the recital applies only to human health, but they believe that in vitro and in silico data should be mentioned as well, next to animal and human data. Moreover, for consistency with the wording used in the criteria, "scientific evidence" should be replaced by "scientific data". Finally, this Member State believes that the provision on GR is too wide and that it is not in line with the principles of Regulation (EC) No 1107/2009. On the provision regarding biological plausibility, this Member State would like to delete the text referring to "internationally agreed guidelines", because they fear this can be interpreted as the OECD guidance on the Adverse Outcome

Pathways (AOP) conceptual framework. In their opinion this would not be appropriate because it would further increase the burden of evidence required to identify EDs.

One Member State indicated that it could support the criteria, provided the amendment to point 3.6.5 is put back on the table and a precise timetable concerning the discussions of this amendment is provided by the Commission. For the moment, it abstains, but could support the criteria if this is done.

One Member State and one EEA country regretted that the Commission had not taken into account their comments, in particular concerning their opinion that the burden of evidence required by the criteria is too high and that the criteria lack precaution and consistency with other legislation. As regards the revised provision on biological plausibility, they reiterated that they would like the criteria to be able to identify EDs for which not enough evidence is available and that the criteria should mirror the fact that science is not yet ready to establish a causal link between the endocrine mode of action and the adverse effect. They also regretted that the wording "read across" is not explicitly mentioned in the criteria, considering cases where not enough evidence would be available on either the adverse effect or the endocrine mode of action. This EEA country expressed concerns that adverse effects may not be identified if the mode of action is not known. On the provision on GR, this Member State stated that despite the clarifications made with the revised recital, they believe the current text still mixes hazard identification and risk management issues. This Member State agrees that GR should be given the possibility to be approved, but that the considerations of risk management should be separated by those of hazard identification. Finally, this Member State believes that "phylum" should be replaced by "order" because the taxonomic phylum is too wide and will not allow adequate protection of the environment.

The Commission explained that they are aware of the concerns of two Member States and one EEA country, as their points were already raised in all previous meetings. The Commission had already widely explained why it disagrees with their views. Regarding the proposal to reduce the scope of the GR provision to the taxonomic "order", the Commission reiterated that this would make the provision useless. The Commission reminded that the scope of the GR provision has been already reduced as much as possible compared to the initial proposals from Member States, which was to define non-target-organisms as non-target-vertebrate-organisms. The Commission clarified that the international guidelines mentioned in the provision on biological plausibility refer to the GD which is currently being developed by the European agencies ECHA and EFSA, with the support of the Joint Research Centre (JRC). A more specific reference to a GD was not added in the criteria to be able to consider any further revision or development of that GD. On the question of read across, the Commission reminded that this approach is never mentioned in Regulation (EC) No 1107/2009 or Regulation (EU) No 283/2013 and thus it would be inappropriate to introduce this concept in the criteria. As regards the concern that adverse effects may not be detected if tests on the mode of action are not available, the Commission reminded that in the impact assessment report it is clearly documented that most pesticide active substances known to have endocrine disrupting properties today, have been already removed from the market during the past years because of their adverse effects, even without knowing their specific mode of action.

One Member State appreciated the efforts of the Commission to accommodate all comments from Member States, which were even coming from opposite positions. This Member State appreciates the clarification made to recital 4 and 7, although on recital 7 they would suggest the Commission considering splitting this long recital in two parts, one addressing the hazard identification part and the second one addressing the risk assessment issues.

One Member State thanked the efforts made by the Commission in finding a qualified majority. They indicated they will support the Commission proposal on the criteria, provided the amendment to point 3.6.5 is not re-introduced.

The Commission reassured that the GD development is progressing well, despite a slight delay with respect to the original time planning. Therefore, it can be expected that a GD (or at least a very advanced draft GD ready for use) would be available when the criteria become applicable. The Commission invited EFSA to give an update on the GD development. EFSA indicated that they received over 1000 individual comments during the first round of consultation of the Consulting Group. The agencies are now analysing these comments and will have a consolidated version ready for the second commenting round which is expected to be from mid-July until end August 2017. In September, the agencies will analyse and address the comments received. A consolidated revision of the GD is expected to be ready by early October 2017 for public consultation.

The Commission addressed the question coming from four Member States on when the text on the amendment to point 3.6.5 would be tabled. The Commission recalled that the amendment was initially included in the same legal text as the criteria. In December 2016, the criteria were split from the amendment in order to give Member States the possibility to express their views separately on these two aspects. The decision to keep the two texts separate is still valid. The Commission reassured Member States that it will resume work on the amendment to point 3.6.5 once the criteria are adopted. The postponement was decided to focus the discussion first on the criteria. The exact timing depends on when a qualified majority for the criteria is reached.

The Commission asked the Member States to express their indicative vote in a tour de table on 17 May. It then invited the delegations not supporting the criteria due to the absence of the amendment to point 3.6.5 to get back to their capitals and see whether with the new information provided (the Commission reassures that it will resume work on the amendment to point 3.6.5 once the criteria are adopted) a change in position could be expected on 18 May.

On 18 May, the Commission presented and circulated a further revised text where some suggestions on recital 4 and recital 7 were taken over. The Commission asked the Member States to express their indicative vote in a tour de table and the positions of Member States were the following:

15 Member States supporting;
8 Member States abstaining, 7 Member States because the amendment to point 3.6.5 is not tabled and 1 Member States because of the GR provision;

3 Member States against, 2 Member States due to too high burden of evidence required and 1 Member State because the amendment to point 3.6.5 is not tabled;
1 Member State no position.
2 Member States abstained, but could support provided the Commission makes an additional commitment (besides the commitment to resume the discussion on the amendment to point 3.6.5 when criteria are adopted) that the EFSA/ECHA GD concerning the implementation of the criteria will be subject to the advisory procedure for endorsement.

The Commission informed that a formal vote will not be taken during this meeting and that a new meeting is planned (30 May 2017, subject to confirmation). On that day, the intention would be to take vote and not reopen detailed discussion.

Vote postponed

M.01 Scientific publications and information submitted by stakeholders.

A letter from the European Crop Protection Association as well as several letters from Pesticide Action Network for distribution to the Committee were uploaded on CIRCABC.

M.02 AOB

Germany informed about a planned workshop concerning the future of harmonised human health assessment for plant protection products.

M.03 Date of next meeting.

The next meeting was confirmed as 19-20 July 2017.