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 19 JULY 2017 - 20 JULY 2017

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/726e71b2-23c2-4cf3-ad04-480dbc372284*

A.01 Summary Report of previous meetings.

The Committee was informed that the summary report from the meeting held in May had been published and that the publication of the report from March was delayed.

A.02 New active substances:

1. New admissible dossiers to be noted:
   i. 24-Epibrassinolide

One new admissible dossier was noted - 24-Epibrassinolide which is an elicitor and plant activator. The rapporteur Member State is Austria and the applicant is Suntton. Admissibility was reported to the Commission on 30 May 2017.

2. Exchange of views on new European Food Safety Authority (EFSA) conclusions:
   i. Beauveria bassiana strain IMI389521

The Commission explained the points raised in the EFSA Conclusion on this substance and asked the Member States to give their view on possible risk mitigation measures that would prevent potential consumer exposure to secondary metabolites through infected insects present in grain stores when treated with *B. bassiana*.

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

No items raised.

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play

The Commission informed about the follow up to the letters sent to Member States in February 2017 who are in delay with the renewal assessments of active substances

included in the AIR III programme. The most frequently reported reasons of the delays were explained: the 12-month assessment period is too short considering the increasingly complex assessments, the quality of the dossiers is sometimes poor, the re-assessment of old studies takes considerable time, the size of the dossiers, more than one dossier per active substance, alignment with classification and labelling, absence of guidance and resource problems.
The Commission informed that for substances included in the AIR IV programme where the deadline for application has already passed, 75% of the substances have received an application for renewal.
The Commission has commenced the work with the fifth renewal programme which concerns 61 substances that expire between 2022 and 2024. These substances have already been evaluated once by Member States and have undergone a peer-review by EFSA. The Commission will invite Member States to a meeting where the allocation of rapporteur Member States for the AIR V programme as well as re-allocation of substances included in the AIR IV programme where the UK is currently the RMS will be discussed. Member States were invited to send their preferences on substances for which they could act as a RMS by 1 September.

2. Exchange of view on EFSA conclusions:

i. Mecoprop-P
Member States were invited to provide comments on the EFSA conclusion published in April 2017 in the view of the renewal of the approval of Mecoprop-P.

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

iii. Propineb
The Commission proposes the non-renewal of propineb due to the main data gap on consumer exposure risk assessment. The draft review report and comments received from the applicant have been uploaded to CIRCABC and Member States were invited to send their comments/positions by 15th September 2017. The RMS expressed its views that a safe use has been identified.

iv. Pseudomonas chlororaphis strain MA342
The Commission seeks not to renew the approval of this active substance. Comments received from Member States have been uploaded to CIRCABC. The Commission presented the arguments put forward in the position paper submitted by RMS and co-RMS. Member States were invited to send their comments/positions on proposed non-renewal by 1 September 2017.

v. Iprodione (no discussion – only short information update for Member States)

vi. Oxasulfuron
The Commission seeks not to renew the approval of this active substance. Some further comments from the applicant and feedback from Member States have been made available to Member States through CIRCABC. Member States were invited to send their comments/positions on proposed non-renewal by 1 September 2017.

vii. Thiram

Member States were informed that following comments received since the May meeting and following a full examination of all evidence currently available, that a proposal for the non-renewal of approval of thiram had been made. Member States were asked to consider the proposal and provide details on any acceptable risk assessments for birds and mammals and to provide further comments or positions by 1 September 2017.
Member States were also made aware of a significant number of letters of support for the seed treatment use of thiram from seed treatment operators in the EU. Furthermore, a number of position papers had been made available by the applicants ahead of the meeting and had been uploaded to CIRCABC. The Commission informed Member States that all information was being carefully considered for decision making.

viii. Bifenazate

The Commission seeks not to renew the approval of this active substance. Some further comments from the applicant and feedback from Member States have been made available to Member States through CIRCABC. The Commission informed that RMS SE will be contacted regarding the possibility to provide an extra calculation of the risk to birds, mammals and non-target arthropods for the lowest representative use rate. Member States were invited to send their comments/positions on the proposed non-renewal by 15 September 2017.

ix. Bentazone

The Commission informed the Member States about the current status of the proposal for bentazone.

4. Update on the decision making for picoxystrobin

Member States were reminded that the non-renewal of approval of picoxystrobin had been referred to the Appeal Committee following the May PAFF Committee meeting where no opinion on the proposal was reached by Member States. The Appeal Committee was held on 12 July 2017. Member States also failed to reach an opinion at the Appeal Committee and therefore the Commission would now decide how to proceed.

Member States were reminded that following a decision to non-renew the approval that there would be separate discussions in the section of the Standing Committee on pesticide residues to consider action required on maximum residue levels (MRLs).

A.04 Confirmatory Data:

1. Bifenthrin

As it shows that the recolonization of non-target arthropods in-field cannot be adequately mitigated and considering the shortcomings identified in the studies on bioaccumulation/biomagnification, the Commission intends to propose a restriction of the approval to uses in greenhouse only. That view has already been defended by several Member States. A formal act in that sense will be proposed once the internal agreement and TBT procedures are finalised.

2. Thiamethoxam
3. Clothianidin
4. Imidacloprid

Points A.04 02-04 were discussed together.

The Commission informed the Standing Committee of the current status of the procedures for the three drafts. Currently the legal drafting of the three drafts is being finalised after which the drafts will be notified to the World Trade Organization.
The Commission informed the Standing Committee of further comments received from stakeholders.
Feedback from Member States was made available on CIRCABC. One Member State indicated their comments were not uploaded on CIRCABC. This will be corrected and the comments will be included in the folder of this meeting together with a late comment sent in during the meeting by another Member State.
A motion of resolution against each of the three drafts was tabled by MEP Girling in June in the ENVI Committee. All three motions were rejected.
One Member State indicated sending further comments and supports the continued use on sugarbeet and potato. One Member State indicated support for the drafts. One Member State supported quick decision making on this issue but indicated that high quality coating techniques were not taken into account. One Member State informed about national cross-cutting measure taken to ban neonicotinoids. The drafts point in the same direction.
One Member State, supported by 2 Member States, inquired on the Bee Guidance Document and repeated the need for an expert meeting on this topic. The Commission indicated that this issue is being explored with EFSA. The growing demand from Member States on a working group to revise the Bee Guidance Documents is understood. The EFSA reminded that the list of bee attractive crops was established with Member States experts.

5. Tetraconazole (review report to note)

The amended review report was noted.

6. Cyflumetofen (no news, written comments before 15/9)

Member States were invited to provide comments on the draft regulation restricting the conditions of approval of cyflumetofen, following the assessment of the confirmatory data.

7. Napropamide (review report to note)
The amended review report was noted. One Member State however expressed the opinion that the data do not fully address the aquatic risk and stated that there are remaining concerns as regards the groundwater metabolite ‘NOPA’.

8. Malathion

Due to the identified high risk to birds, the Commission intends to propose a restriction of the uses to greenhouse only. That view has also been defended by several Member States, while some might opt for a full ban. The suggestion by the

notifier of a combination of changes in the GAP and restrictions in rates and timing has been carefully examined but has not been considered acceptable. A formal act will be proposed once the internal agreement and TBT procedures are finalised.

9. Dithianon (no discussion)

No discussion took place.

10. Tri-allate

The Commission will try to propose an amended review report by the next meeting. An important issue is the presence of one soil metabolite and the relative weakness of the submitted toxicological data base. The notifier promised further evidence in these fields.

11. Eugenol

This dossier is related to the two following as they are defended by the same notifier and presented on the market as a mixture of all. There are common weaknesses identified in all dossiers, such as the comparison to background of the levels of (human and environmental) exposure. Nonetheless, each substance must be considered on its own merits. For eugenol only, the presence of methyleugenol needs careful consideration

12. Geraniol

See above.

13. Thymol

See above. In this particular case, also the absence of agreed toxicological reference values should be noted.

14. Triazole Derivative Metabolites (TDM)

The Committee was informed that the Commission had mandated EFSA to organise a further peer review of certain aspects of the assessment giving a deadline for a Conclusion of 30 June 2018.

15. Straight Chain Lepidopteran Pheromones (SCLP)

The Commission submitted a draft revised review report referring to the EFSA conclusions on confirmatory information which indeed confirm the set conditions of approval of SCLP to be used in dispensers . The report includes also a new compound belonging to the group. MS took note of the rev.13 of the SCLP review report.

16. Terbuthylazine

The Committee was informed that the EFSA Conclusion on aspects of confirmatory information related to groundwater contamination had been published and that the

Commission was now considering the next steps. Member States were invited to submit any early views or comments.

17. Iprovalicarb

It shows that EFSA and Member States consider the matter adequately solved. Therefore the Commission has just uploaded an amended review report which will be re-presented for note-taking at the next meeting.

18. Metazachlor

In its conclusion EFSA concludes that two metabolites must be considered relevant and, although the good quality of certain monitoring studies is not contested, these studies are insufficient to overrule the FOCUS modelling. As both metabolites leach in all scenarios, the option of a withdrawal of the substance must be considered. Greenhouse use is not an alternative given the supported GAPs (herbicide in rape, rapeseed and forestry).

19. Pyretrins

Commission informed on the outcomes of the peer review of the submitted studies which have confirmed no genotoxicity of parent compound, no genotoxic effect due to inhalation, positive representativity of pyrethrin I with respect to fate and behaviour. However, still pending data for the residues definition due to pending assessment of toxicity of metabolites. The Commission taking into account the low toxicity profile of the parent compound would consider further submission of an appropriate battery of in vitro tests as soon as possible to allow also the review of MRLs under Regulation 396/2005. However, a decision has to be taken whether not to restrict approval. To note that the renewal of pyrethrins is scheduled under AIR 4 programme and a dossier should be submitted by February 2020. Member States were invited to send their comments/positions on proposed action by 15 September 2017.

20. Acetic acid

Commission informed Member States on a draft review report that was also uploaded to CIRCABC. Commission proposed to confirm the conditions of approval of the active substance in the light of the positive outcome of the assessment of confirmatory studies. Member States were invited to send their comments/positions on the draft by 15 September 2017.

21. Picloram

It shows that EFSA and Member States consider the matter adequately solved. The Commission had already uploaded an amended review report which will be re-presented for note-taking at the next meeting.

22. AOB

No issues were raised.

A.05 Article 21 Reviews (no news).

No discussion took place.

A.06 Amendment of the conditions of approval:

1. New admissible dossiers to be noted:

i. Fenazaquin

Member States were updated on the status of the dossier. Some further comments from the applicant have been made available to Member States through CIRCABC. The applicant claims that given the refined risk assessment for aquatic organisms, a safe use can be demonstrated for fenazaquin, and that the current restrictions can be lifted. Member States were invited to send their positions on lifting the restrictions in view of the refined aquatic risk assessment by 15 September 2017.

2. Exchange of view on EFSA conclusions:

No new EFSA conclusion available

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

i. Penflufen (no news, written comments before 15/9/2017)

Member States were invited to provide comments on the draft regulation lifting the restriction to the treatment of potato tubers in the approval of penflufen.

A.07 Basic substances:

1. Pilot projects: state of play

The Commission informed that the next meeting of expert group on Basic substances will be held on 11 October 2017, Member States who have not yet done are invited to nominate delegates by end of August.

The Commission brought to the attention of delegates the ongoing commenting phase on the last pilot project Quassia for which the application was "frozen" after submission of first comments from MS and EFSA. Indeed, the application had to be completed through collation of further information in particular on residues exposure. The applicant IFOAM as the substance is of particular interest in organic farming has submitted a completely reviewed application end of 2016 which was then completed by applicant in line with template guidance and now circulated for comments by EFSA.

2. New dossiers received (only for information)

i. *Valeriana officinalis* extract

The Commission informed the Member States of the receipt of an application for this substance for use as a plant elicitor in grapevine, fruit trees and vegetables.

3. Exchange of views on EFSA Technical Reports.

i. *Saponaria officinalis* root extract

The Commission informed the Member States on the points raised in the EFSA technical report and asked MS to provide information on the use of the substance and/or tahini halva (it which it is used) as a foodstuff in their MS.

4. Draft Review Reports for discussion:

i. Equisetum (extension of use) :

The Commission informed on the revised review report for equisetum to extend the uses to strawberries, raspberries and potato. Comments received by one Member State on the structure of chapter on supported uses have been incorporated. MS took note of the revision 7 of the review report .

ii. Potassium sorbate

The Commission seeks a non-approval of potassium sorbate as a basic substance, because of the contribution it would have to the exceedance of the Acceptable Daily Intake (ADI) that was reported in the scientific opinion of the EFSA ANS panel in 2015. The applicant, whose response was made available through CIRCABC, had no comments on the proposal. MS were asked to send in their opinion on the proposal by 1 September 2017.

iii. Beer

The Commission seeks approval of beer as a basic substance for use as a molluscicide. Member States were asked to send in their opinion on the proposal by 1 September 2017.

iv. Mustard powder

The Commission seeks approval of mustard seed powder as a basic substance for use as a fungicide for seed treatment. Member States were asked to send in their opinion on the proposal by 1 September 2017.

A.08 Exchange of views on Guidance Documents:

1. Template to be used for Assessment Reports (SANCO/12592/2012 Rev. 1)

No discussion.

2. Guidance Document on Data Protection (SANCO/12576/2012 Rev. 2.2)

No discussion.

3. Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010 Rev. 10)

No discussion.

4. Guidance document on the presentation and evaluation of plant protection product dossiers in the format of a (draft) Registration Report (SANCO/6895/2009 Rev. 2)
No discussion.

5. Terms of Reference of the Working Group on Post Approval Issues from the Standing Committee on Animals, Plants, Food and Feed: section Pesticide Legislation (SANTE/11102/2017 to be noted)
The draft Terms of Reference of the Working Group on Post Approval Issues were presented and several MS and EFSA made comments on the possible overlapping remit of this group with the work of the Pesticide Steering Network hosted by EFSA. Some concerns were raised also on EFSA not being involved in discussions on procedures for active substances. Some MS asked for a more detailed clarification on the decision making process for the guidance documents developed or updated by the PAI group. Finally, some MS asked for a closer cooperation between the PAI group, the SCoPAFF and other WGs hosted by the Commission.
Commission reminded the Member States that a large majority of the Member States attend the PAI group where the document was extensively discussed and finally agreed without major objection. It was stated that EFSA as other agencies or stakeholders can be invited to the PAI group on specific issues. Member States were invited to provide comments on the documents and more specifically on three questions: (i) should the PAI group work only on post-approval issues or on all procedural guidance, (ii) should EFSA be part of the PAI group or only invited for specific issues dealing with peer-review processes, (iii) should the remit of PAI be discussed as a stand-alone point or merge with the general discussion called by some Member States under point M 02.01. EFSA was also invited to comment on the document.

6. Report from the Danish EPA workshop on data requirements for acute inhalation toxicity testing
A workshop was held by the Danish EPA in Copenhagen to provide MS a possibility to discuss the interpretation and applicability of the data requirement on acute inhalation toxicity for plant protection products (PPP) (Regulation (EU) 284/2013, Annex B, paragraph 7.1.3. condition i)).
While the scope of the issue was unanimously shared amongst the participants, the interpretation and possible solutions to fix the problem were only partially agreed. Different options were laid down for the Commission and Member States to consider.

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

103 notifications have been sent in by The United Kingdom concerning authorisations for products containing glyphosate.

The Committee took note of the notifications.

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

1. Notifications (to be noted)

Three Notifications were received and presented to Member States for taking note: Sinconil (Belgium), Boravi 50 WG (United Kingdom) and CAPTAIN 80 WH (Spain).

Notifications for COMRADE (Spain) and for LUMAX (Czech Republic) were rejected from note taking, as obligatory mutual recognition does not apply in both cases. The Commission, however, notes that the reason provided in the notification for COMRADE would not be valid in the frame of Article 36(3).

The Member States took note of the notifications from Belgium, Spain and The United Kingdom.

2. Information from Germany concerning recent national case law

Germany informed the meeting about recent case law: The Administrative Court Braunschweig has ordered Germany to accept in a mutual recognition procedure the assessment and decision of the Member State who granted the authorisation and shall abstain from repeating the assessment.

The Commission welcomed this information and fully shares the view of the Court in Braunschweig. As the issue was brought up on rather short notice, a discussion is postponed and Member States are invited to prepare their positions.

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

Emamectin (Belgium)
Spirotetramat (Belgium)
Cyantraniliprole (Belgium)
Abamectin (aka avermectin) (Estonia)
Quinoclamine (Finland)
Chlorantraniliprole (Finland)
Quizalofop-P-ethyl (Finland)
Lambda-Cyhalothrin (Germany)
Etofenprox (Greece)
Fenamiphos (aka phenamiphos) (Greece)
Cyantraniliprole (Greece)
1,3-Dichloropropene (Greece)
Pyrimethanil (Greece)
Fluopyram, Tebuconazole (Greece)
MCPA (Greece)
Bentazone (Greece)
Ethylene (Greece)
Lavandulyl senecioate (Greece)
Thiacloprid (Latvia)
Kieselgur (diatomaceous earth) (Latvia)
Fenpyroximate (Lithuania)
Thiophanate-methyl (Lithuania)
Etridiazole (The Netherlands)

Spiromesifen (Portugal)
Beauveria bassiana strains ATCC 74040 and GHA (Portugal)
Tebuconazole (Portugal)
Pyrethrins (Portugal)
Bentazone (Portugal)
Fludioxonil (Portugal)
Phosmet (Portugal)
1,3-Dichloropropene (Portugal)
Alpha-Cypermethrin (aka alphamethrin) (Slovenia)
Pendimethalin (Spain)
Propanil (Spain)
Cypermethrin (Spain)
Thiophanate-methyl (Spain)
Cyantraniliprole (United Kingdom)

The Committee took note of the notifications submitted by Belgium, Estonia, Finland, Germany, Greece, Latvia, Lithuania, The Netherlands, Portugal, Slovenia, Spain and The United Kingdom.

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

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

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

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

The Commission requested Member States to assure entering 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.
The Commission recalled its concerns about the repeated and continued authorisation of products containing the substances clothianidin, imidacloprid or thiametoxam in some Member States following the restriction of approvals of these active substances

in 2013. These concerns were raised repeatedly at meetings of the Standing Committee since then.

As announced earlier, the Commission is currently preparing a mandate to EFSA, in line with the provisions of Article 53(2), to provide assistance. The mandate concerns those authorisations for the three substances which were granted repeatedly since 2013 for use in major crops; authorisations which were granted only once or in minor crops. The Commission will transmit all available information to EFSA; however, the Member States concerned might be contacted by EFSA in case additional information (e.g. underlying raw data) would be necessary.

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

The action plan of the Pesticide Steering Network concerning improving the pesticide peer review was further discussed in a teleconference on 21 June. A follow-up meeting is planned for 24/25 October.

Some amendments were made to the guidance document concerning endocrine disruption and a second consultation round (Member States and stakeholders) was launched on 17 July and will be open until 31 August. EFSA intends to carry out a public consultation in the guidance document in November and a workshop for Member States to discuss case studies in January 2018. So far, only one Member State has volunteered.

EFSA decided to reduce the number of new peer reviews to be started to 4 per month, in order to assure a high quality of the review. Priority will be given to new active substance.

Meetings of the PPR Panel were scheduled for July and September. The Panel renewal is ongoing.

An expert discussion concerning endocrine disrupting properties of glyphosate was held in June. All experts agreed that glyphosate has no EATS (oestrogen-androgen-thyroid- or steroidogenesis)-mediated endocrine disrupting properties. The consultation of Member States is ongoing. However, from EFSA's point of view the data gap of the initial conclusion has therefore adequately been addressed and no concerns are identified.

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.

A.14 Report from working groups:

1. Plant Protection Products Application Management System (PPPAMS)

There was no news to report since the May meeting. The Commission informed Member States that once the new version of PPPAMS was ready for testing that Member State users would be contacted with further instructions.

2. Post Approvals Issues group (PAI)

The PAI group met in June and discussed several guidance documents, namely GD on article 43, GD on data protection, GD on zonal assessment and mutal recognition. The dRR working group also reported on the case study performed using the new template for dRR.

The terms of References were discussed (see also point A. 08.05).

Member States were informed that documents, including minutes of the meetings, are uploaded on CIRCABC.

Member States were also reminded to regularly send updates about the on-going processes on confirmatory data where they act as RMS.

3. Sustainable plant protection experts group Dutch proposal (no meeting)

MS were asked to send in the information requested by e-mail for the report of progress implementing the actions described in the implementation plan on low-risk products and IPM by 8 September 2017.

4. Working group on Biopesticides

The WG was reconvened in May. External experts on secondary metabolites, skin and respiratory sensitisation and pathogenicity were invited to share their knowledge.

The way forward on secondary metabolites was discussed. A specific commenting period of the discussion paper drafted by the working group will be launched in the coming weeks.

The WG discussed the necessity of the precautionary phrase in the data requirements on potential sensitising properties of micro-organisms.

The next meeting will take place in October.

5. Working group on Seed Treatments (no meeting)

No discussion.

6. Working Group on Co-formulants

The WG was reconvened in July and discussed the general approach and two draft acts on unacceptable co-formulants. One act sets detailed criteria and the procedure to identify unacceptable co-formulants and the second act provides the first batch of unacceptable co-formulants in Annex III.

The need for additional inputs from REACH competent authorities and ECHA was identified.

The next meeting will take place in October.

7. Working Group on low-risk criteria

The Commission informed on the main items discussed during the recent meeting of 4 July 2017. In particular, experts agreed on the need for an implementing guidance concerning the new low risk criteria with a view to clarifying the link with provisions of Article 47 on low risk plant protection products. The group prepared a paper in which the experts express their concern that following the detailed classification criteria used as exclusion criteria in the new low risk criteria will probably lead to the

exclusion of certain semiochemicals from the low risk category.
The Commission recalled that a decision whether a substance is considered as low risk solely depends on its actual properties and does not depend upon its affiliation to a certain category of substances, like semio-chemicals. This is particularly the case when the use of such substance would result in a higher concentration in the environment than the natural background.
The Commission underlined that, although straight chain lepidopteran pheromones (SCLP) have been approved as a group, it is not possible to approve them all as low risk substances by default, as some of them are proposed for classification for toxicity to aquatic organisms and/or skin sensitizer Category I (on the basis of the worst case data).
Decision on low risk properties have to be taken on a case-by-case basis and all information available will be taken into account in order to get a complete picture. Member States agreed to the Commission considerations.

Finally, Member States were informed on the work ongoing to establish a Commission Notice, including a non-binding list of substances approved under Directive 91/414/EC as potentially low risk. The preparatory screening performed by the Commission was presented in the Working Group and is open for commenting by the WG. The Commission will present the Commission Notice in one of the upcoming meetings of the Standing Committee. One Member State underlined the importance of increasing the availability of low-risk products and thanked the Commission for the work done so far. Another Member State asked the Commission whether it was possible to include in the list also the active substances officially approved as low-risk substances to which the Commission responded that these substances are already separately listed in Regulation (EC) No 540/2011, section D.

A.15 OECD.

The Commission gave a brief update on the meetings under the umbrella of the OECD Working Group on Pesticides which took place in the week of 26 – 30 June.

A.16 Court cases.

No news on court cases.

A.17 Endocrine Disruptors.

The Commission informed Member States about the steps which follow the positive vote on the ED-criteria taken at the PAFF the 4th of July and recalled on the commitments given at previous meetings. The Commission indicated that the text agreed would be sent to the Council and the European Parliament (EP) for scrutiny today or latest next Monday. Council and EP will have three months to examine it before the final adoption of the text by the Commission. The text will enter into force 20 days after its publication in the Official Journal and be applicable six months after this, so that scientific ED-criteria could be applicable mid of 2018. The Commission reiterated that these criteria would apply to all on-going procedures, including those

currently at Rapporteur Member States, EFSA, or where a regulatory decision is pending at PAFF.

The Commission recalled that, as mentioned in its press release of the 4th of July, the positive vote on the criteria is a step forward and to be put in a bigger context as the Commission intends to revise the ED-strategy, including also other sectors beyond PPP and biocides, and to invest into research which focuses on EDs. Details on these activities can not yet been given but internal work is already on-going.

The Commission informed that the discussions on the delegated act for the ED-criteria under the Biocides legislation (Regulation (EU) No 528/2012) were concluded at the meeting the 12 of July and that draft minutes of the meeting are published on the ED-website of DG SANTE. At this meeting, the growth regulator provision raised some discussion, but the Commission intends to adopt the delegated act with the criteria identical to the PPP-criteria in terms of content aiming at horizontal criteria between the PPP and BP sectors. The adoption of the act is intended soon in order to submit it for scrutiny in August. In this way, the scrutiny period for both the PPP and the BP act would run in parallel.

As regards the implementation of the new ED-criteria, the Commission confirmed that the drafting of the guidance document by EFSA and ECHA is progressing well, and that the 2nd consultation of MS and stakeholders has been launched the 17 of July and lasts until end of August. A public consultation will be launched in autumn, once at least one of the acts on the ED-criteria is published, and a workshop with Member States is planned for early 2018. If everything works as planned, a guidance document is expected to be available at the same time the ED criteria are applicable.

Further, the Commission informed that a legal act amending the Implementing Regulating 844/2012 is currently undergoing Interservice Consultation and is expected to be discussed at the next PAFF. This act is needed in order to set procedures for the renewals of active substances currently on-going and will be subjected to the "feedback mechanism", allowing stakeholders and general public to comment on it. Based on a question of one Member State, the Commission explained that a guidance on the procedures for new active substances is in preparation, follows the same rationale as the draft implementing act, and may be available for discussion with Member State at the same time.

The Commission further clarified that the list of active substances listed in the impact assessment as falling under any of the options, are based on preliminary results of the screening study and that the final report of the screening study shows a different listing for some of the active substances. The Commission also reminded about the status of the screening, and referred to the disclaimer in the impact assessment report and the screening study report.

One Member State urged the Commission to table the text on the amendment to the derogation as soon as possible and asked for an indicative timing. The Commission reiterated its commitment expressed in previous meetings, and indicated that it will be tabled at the 1st possible occasion after the ED-criteria passed scrutiny and are adopted.

Another Member State asked for a clear communication which stresses the difference between before and after the ED-criteria.
Another Member State wondered if for pending decisions on active substances where and EFSA Conclusion is already available, and restricted adoption with confirmatory data would not be an alternative. This Member State also wondered if the confirmatory data set in the past years as regards EDs, whose submission would be triggered now with the new ED criteria, would not merit a revision or a specification in order to have a smooth process at RMS or EFSA level. The Commission thanked for these contributions and would reflect on them.

A.18 Minor Uses.

It was recalled that the current funding of the Minor Uses Coordination Facility (co-funding by the Commission and three member States) will expire on 14 April 2018. Therefore, the Facility has developed a concept towards a long-term funding which foresees a stronger participation of Member States through a system of voluntary contributions. In order to create a balanced system, these contributions should take into account the size of the respective Member State.

This initiative was welcomed by the meeting. The Commission clarified that after the initial three years it is no longer possible to continue the funding and Member States are asked to step in. Several Member States iterated their willingness to explore the possibility to contribute. Member States asked the Commission to prepare a formal letter explaining the background and asking for funding.

A new release of the European Minor Uses Database (EUMUDA) was officially launched on 28 June. It builds on the structure of the already existing EUMUDA, but the content was completely revised. Moreover, EUMUDA is now fully compatible with the Plant Protection Products Application Management System (PPPAMS). An introduction into the look and feel and the functionalities of the database was given.

A.19 Interpretation issues:

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

   i. Plant strengtheners (request by Lithuania)

Due to time constraints, this point was not discussed and will be examined at a future meeting.

2. Questions and answers

No discussion.

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

1. Status of harmonised classifications

An updated table with the status of harmonised classifications was made available on CIRCABC. This point was not discussed during the meeting.

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

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

A.21 Glyphosate.

- State of the dossier
- Draft Review Report and Regulation for discussion

See the separate extract on glyphosate published on the Europa webpages shortly after the meeting:
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_phyphosate_paff_meeting_sum_20170719.pdf

A.22 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

No discussion.

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 Member States that the consultant Ecorys and Linge have been selected to perform the external study for the evaluation. The kick-off meeting was held on 3 July 2017 and the study will run for 12 months. Several consultations will be carried out, some specifically with the objective to gather information from Member States.

In the framework of the study, a workshop will be organised on 12 September in Brussels. Member States were invited to participate, however, due to limited capacity there will be a maximum of 10 Member States representatives at the workshop. The Member State representatives need to represent both the legislation and the residue section. Member States were requested to send their interest to participate in the workshop by 4 August 2017.

A.24 Exposure of florists to plant protection products from cutflowers.

Four Member States indicated the need to keep this point on the agenda of this meeting. One Member State informed that their national Ministry of Social Affairs is checking this issue. Member States were therefore requested to verify their national

legislation regarding worker protection. The Commission will contact DG Employment on this subject.
Member States indicated the issue lies primarily with import of flowers, certainly for residues of non-approved substances. Member States indicated that the expertise of assessing risk to workers from exposure to pesticides is within this Committee.
The Commission agreed to keep this point on the agenda. Member States were requested to send further comments and feedback on national regulation regarding worker protection by 15 September 2017.

A.25 Pepino Mosaic Virus – use by tomato plant propagators.

The Commission informed Member States about two e-mails it received containing concerns about the use of mild pepino mosaic virus (PMV) isolates by tomato growers. The e-mails were made available to the MS through CIRCABC. The two parties are concerned that the use of mild PMV isolates by tomato propagators may lead to the spread of PMV to Member States where it is not prevalent and that virulent recombinants or mutants may form at the tomato plant propagator that may spread to tomato growers. They propose to restrict the use of pepino mosaic virus to tomato growers.

The Commission noted that PMV is not classified as a quarantine pest and that there currently are only emergency measures in place for seeds. Seeds may only be placed on the market when free of PMV. Tomato plants infected with PMV can be placed on the market and move freely within the EU.

The Commission further explained that the concern with regard to recombination or mutation was addressed in the RMS assessment report and the EFSA Conclusion on which the approval of the pepino mosaic virus strains is based. The assessment report contains a list of risk mitigation measures to prevent the spread of virulent recombinants/mutants. Therefore, the Commission currently sees no reason to review the approval decisions at EU level.

The Commission requested Member States to pay particular attention to the concerns raised and set appropriate risk mitigation measures at zonal/national level as part of the product authorisation and consider whether that should include a restriction of the use to tomato growers or that other measures are sufficient. Explicitly for tomato seed production, the existing EU requirements must be taken into consideration.

One Member State wondered whether risk mitigation measures on national level would be sufficient, considering plants can be moved to other Member State after vaccination. Another Member State consulted their stakeholders and they do not see a particular concern with regard to the use of mild PMV isolates by tomato plant propagators.

The Commission asked Member States to give their views on the Commission's view by 15 September 2017.

A.26 New mandate for a Working Group (WG) to set up a procedure to assess new variants of approved active substances.

The Commission presented a mandate for a new group to work on a procedure to assess new variants of approved active substances. Currently a procedure is set for the assessment of equivalence of alternative sources for an approved active substance but there is no harmonised procedure for the assessment of new variants of an approved active substance, where these variants are covered by the approval. Member States and EFSA were invited to comment on the draft mandate.

A.27 2,4-D - Revision of AOEL and ADI.

As to ensure a high level of human protection and for reasons of consistency, it seems necessary to implement the reference values (including ARfD) for 2,4-D as they have been defined in the EFSA conclusion as regards 2,4-DB. Moreover, it is important to harmonise the national approaches which tend to diverge. As a consequence, the Commission will propose for the next meeting a review report for 2,4-D amended accordingly for note-taking.

A.28 Workshop on Harmonized Human Health Risk Assessment (BfR), Berlin, 23 – 24 November 2017.

The Commission referred to the Workshop "What does the future hold for harmonized human health risk assessment of plant protection products?", which will take place at the German Federal Institute for Risk Assessment (BfR) in Berlin the 23rd and 24th November 2017, and indicated it can reimburse the travel expenses of maximum two 'governmental experts' per Member State. The Commission invited MS to share this information with their colleagues and to ask them to register to the workshop via the specific registration form available on-line (link will be circulated by the Commission in the next days) until the 15th September 2017.

A.29 Protection goals for environmental risk assessment – update on next steps.

The Commission indicated that this point was discussed in 2015 but put on hold. The intention is now to resume work on this, with the first concrete steps at risk manager level end of 2017/beginning of 2018. The Commission referred also to a meeting between COM and EFSA which took place in June in order to have an initial discussion, and invited Member States to send any suggestions or comments by 1 September 2017.

A.30 Pest management changes after neonicotinoid and fipronil restrictions: results from a survey (Presentation Joint Research Center, JRC).

The JRC presented the results from a survey on the pest management changes after neonicotinoid and fipronil restrictions.
JRC indicated that an article on this survey in a scientific journal is currently under peer review with publication expected in September.
One Member State inquired about the capability of farmers to judge the presence of wild beneficial insects. JRC indicated that farmers are in general very knowledgeable in scouting for pests but not necessarily for beneficial insects. Two Member States

indicated their interest in knowing the consequences of regulatory decisions as is provided by this survey.
JRC will check with hierarchy if slides can be made available as this might not be allowed by the scientific journal.
EFSA is interested to see if there is a possibility to link the outcome of the survey to monitoring data available at EFSA. JRC indicated this might be possible under the memorandum of understanding of cooperation between EFSA and JRC.

A.31 Initial information concerning Brexit.

The Commission gave an update on the developments concerning Brexit in the field of plant protection products.

B.01 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. 3).

The Commission outlined the proposal and its content. Several Member States were not able to support the proposal as they agree with the approval of the active substance, but only under the condition of confirmatory data. The Commission recalled Member States the report of the European Ombudsman about the application of confirmatory information and the need for the Commission to address the criticism raised there. Several Member States requested to organise a working group in order to shape the application, but at the same time insist that confirmatory data is one element of conditions of approval provided by Regulation EC (NO) 1107/2009.
As there was no qualified majority in favour of the draft, the Commission withdrew the draft and will reflect on how to address the request of Member States to approve the substance with a condition to submit confirmatory data.

Vote postponed

B.02 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 DPX KE 459 (flupyrsulfuron-methyl), in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10317/2015 Rev. 3).

One Member State voted against because it has an existing authorised use that does not result in levels of metabolites in groundwater above 0.1 µg/L. They also cited national monitoring data that supported this position. 3 Member States abstained because they did not consider that the relevance of groundwater metabolites had been fully established. One Member State abstained because they did not consider the

Opinion of the Scientific Committee of EFSA with regards to genotoxicity to be endorsed by Member States. One Member State abstained as they considered that the risks and concerns identified could be solved by looking at new data that was available, via the setting of a confirmatory requirement, and they also questioned the classification proposals for parent substance.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of the active substance beta-cypermethrin, 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/10237/2017 Rev. 1 (formerly SANTE/12481/2015 Rev. 4)).

One Member State abstained as it considered that confirmatory data could be set to address the concerns identified by EFSA.
One Member State voted against expressing concerns about the general lack of insecticides (citing also the future impact of other cypermethrin substances due to the addition of cypermethrin to the priority list of substances in the field of water policy); furthermore this Member State had concerns about the length of time taken to reach a decision.
One Member State voted against as they had concerns about the lack of insecticides and considered that the profile of the substance was not significantly different to other approved pyrethroids and that issues identified could be addressed at national level.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance sodium chloride 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 SANTE/10383/2017 Rev. 1).

The Commission presented the draft, which was voted by the Committee.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation confirming the conditions of approval of the active substance 8-hydroxyquinoline, as set out in Implementing Regulation (EU) No 540/2011 and modifying the Commission Implementation Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of

candidates for substitution (Draft Addendum to the Review Report SANTE/11618/2016 Rev. 0.1).

Several Member States requested to postpone the vote, because the final version of the draft had been made available too late. Two Member States stated that the proposed classification of the Risk Assessment Committee of ECHA should be considered as a relevant new piece of information and thus triggering a full review of the approval of 8-hydroxyquinoline.
The Commission indicated that the case of 8-hydroxyquinoline should be read in a consistent way to the substances listed as candidate for substitution according to Article 80(7) of Regulation (EC) No 1107/2009.

Vote postponed

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance 2,4-DB in accordance with Regulation (EC) No 1107/2009 of the European Parliament and 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 SANTE/10066/2017 Rev. 4).

Two Member States voted against because of subsisting data gaps which, in their view, ought to be addressed through the evaluation at EU-level of confirmatory information to be submitted by the applicant.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance carfentrazone-ethyl in accordance with Regulation (EC) No 1107/2009 of the European Parliament and 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 SANTE/10144/2017 Rev. 3).

A majority of Member States supported the approval of the substance but, at the same time insisted that the substance should be approved with a requirement to submit additional confirmatory data concerning the potential relevance of metabolites in groundwater. Lacking such provision, there was not sufficient support for the Commission draft.
The Commission will reflect on the matter and refers to the discussion that took place under Point B. 01.

Vote postponed

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active

substance imazamox 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 Renewal Report SANTE/10499/2017 Rev. 3).

Two Member States voted against because the confirmatory information was not requested to be assessed at the EU level for important areas of risk assessment.

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 maleic hydrazide, 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/10561/2017 Rev. 2).

Two Member States voted against because the confirmatory information was not requested to be assessed at the EU level for important areas of risk assessment. One Member State voted against due to leaching of metabolites into groundwater. One Member State abstained due to metabolites leaching into groundwater. One Member State abstained because the confirmatory information was not requested to be assessed at the EU level as regards the relevance of metabolites.

Vote taken: Favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance quizalofop-p-tefuryl.

One Member State voted against as it considers that the substance is falling under the cut-off criteria.

Vote taken: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance silthiofam in accordance with Regulation (EC) No 1107/2009 of the European Parliament and 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 SANTE/11799/2016 Rev. 2).

The Commission outlined the draft and its content. One Member State indicated to abstain because of the potential leaching of metabolites. Another one would have voted against for lack of data on birds risk assessment. Several Member States were in

favour of the approval of the substance, but only under the condition that he applicant is obliged to submit confirmatory data.
As there would have been no qualified majority in favour of the proposal, the Commission withdrew the proposal and will reflect on how to address the request of Member States to approve the substance with a condition to submit confirmatory data.

Vote postponed

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance acetamiprid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and 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 SANTE/10502/2017 Rev. 2).

Voted postponed due to the ongoing internal consultation process.

Vote postponed

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances cyflufenamid, fluopicolide, heptamaloxyloglucan and malathion.

One Member State voted against as it considers malathion to be a substance of concern.

Vote taken: Favourable opinion.

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation as regards the extension of the approval periods of the active substances 1-methylcyclopropene, 2,4-DB, beta-cyfluthrin, chlorothalonil, chlorotoluron, cypermethrin, daminozide, deltamethrin, dimethenamid-p, flufenacet, flurtamone, forchlorfenuron, fosthiazate, indoxacarb, iprodione, maleic hydrazide, MCPA, MCPB, silthiofam, thiophanate-methyl and tribenuron.

Two Member States voted against the Draft Regulation as they consider that one or more of the substances may fail to fulfil the approval criteria.

Vote taken: Favourable opinion.

M.01 Scientific publications and information submitted by stakeholders.

No item raised.

M.02 AOB

Thought-starter-paper on structure of discussions in the Standing Committee and its working groups (submitted by DE/NL).
The paper was briefly outlined by Germany and the Netherlands; due to the late submission of the paper and time constraints a more detailed discussion will take place at a later meeting.

M.03 Date of next meeting.

The date of the next meeting was confirmed for 5-6 October 2017.