EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2018)475819

Standing Committee on Plants, Animals, Food and Feed

Section *Phytopharmaceuticals - Legislation*

05 - 06 October 2017

CIRCABC Link: https://circabc.europa.eu/w/browse/d36ff9ae-0fd1-41e0-8ee0-8fec085e3c37

SUMMARY REPORT

A.01 Summary Report of previous meetings.

The Committee was informed that the summary report from the meeting held in March was to be published shortly, the report from May had been published and that the report from July was in progress.

A.02 New active substances

1. New admissible dossiers to be noted:
   a. *Beauveria bassiana* 203
   Beauveria bassiana 203 is an insecticide, the rapporteur Member State is the Netherlands and the applicant is Glen Biotech. Admissibility was reported to the Commission on 20 July 2017.
   Member States took note of the new admissible dossier.
2. Exchange of views on new European Food Safety Authority (EFSA) conclusions:
3. Commission Draft Review Report and Regulation concerning the (non-) approval of:
   a. *Beauveria bassiana* strain IMI389521
   No draft review report was presented yet. The Commission informed the Member States of the comments received by two Member States. The Commission further informed Member States that it will wait for the results of the ongoing study procured by EFSA on the toxicological properties of beauvericin. Member States were invited to share their views by 17 November 2017.

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play

   The Commission informed Member States that an act extending the approval periods for some active substances with a current expiry date in January 2018,

and where a decision will not be made on their renewal before this time, will be presented to the Standing Committee in December.

The Commission gave an update from the working group held on 4 October 2017 on the allocation of substances included in the AIR V programme, i.e. substances that expire between 2022 and 2024, as well as the re-allocation of substances from the UK where the assessment has not yet started. An implementing act amending Regulation (EC) No 686/2012 will be presented to the Standing Committee in December or January.

2. Exchange of view on EFSA conclusions:

   a. Pethoxamid
      The Commission informed the Committee about the recently published EFSA conclusion on the peer review of the renewal of pethoxamid. Member States were invited to send their comments by 27 October 2017.

   b. Mepanipyrim
      This item was discussed under point A.03.p.

   c. Bromoxynil
      The Commission informed the Committee about two main concerns expressed in the EFSA conclusion and of the comments provided by the applicant. Member States were invited to send in their views by 27 October 2017.

   d. Chlorpropham
      The Commission informed the Committee about two main concerns expressed in the EFSA conclusion, a recent paper submitted by the RMS and the comments provided by applicant. Member States were invited to send in their views by 27 October 2017.

   e. Propiconazole
      The Commission informed the Committee that the EFSA Conclusion published in June 2017 was being considered with a view to making a draft available for the December meeting. It was highlighted that several critical concerns and other issues had been highlighted by EFSA. The Committee was given an update on the situation with regards to classification following the proposal of the Risk Assessment Committee of the European Chemicals Agency (RAC) to classify as toxic for reproduction category 1B. Close dialogue between DG SANTE, DG ENV and DG GROW was established on this aspect.
      Member States were asked to provide any initial comments or views by 17 November 2017.

   f. Flurtamone (updated Conclusion published in September 2017)
      Member States were informed that following a mandate to complete the assessment and update the peer review, EFSA had republished an updated conclusion on flurtamone. It was recalled that a proposal had already been made in 2016 for non-renewal of approval following the publication of the EFSA Conclusion. Member States were asked for their comments and views in light of the updated Conclusion.

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

   a. Propineb
   The Commission informed the Committee about the draft review report for non-renewal and that an inter-service consultation is ongoing. In addition, the Commission informed Member States about a position paper submitted by the RMS and other documents provided by the applicant. Information has been submitted to defend a safe use which would have been identified for grape with two pre-flowering applications in the Central zone. The Commission underlined the lack of representative use and the alleged assessed toxicity of the metabolite PDA would be based on documentation available at ECHA and not peer reviewed. Member States were invited to send their views by 27 October 2017.

   b. Pseudomonas chlororaphis strain MA342
   The Commission provided an update of the state of the dossier: the comments received from the Member States, the received support letters and the issues discussed during the meeting with the applicant. The documents provided by the applicant were made available to the Member States. Member States were asked to submit their comments by 17 November 2017.

   c. Oxasulfuron
   The Commission proposed to not renew the approval of oxasulfuron. The Commission provided a summary of the comments received from the Member States and the comments of the applicant on the Renewal Report. The documents provided by the applicant were made available to the Member States. Member States were asked to submit their comments by 20 October 2017.

   d. Thiram
   Member States were informed that since the July meeting a number of additional letters and papers had been received from the applicant and others, plus some additional comments from Member States – all correspondence had been made available to Member States via CIRCABC prior to the meeting.
   It was recalled that no acceptable risk has been identified for birds and mammals and that considering all the information available it seems highly unlikely that the risk can be resolved.
   Therefore, in the meantime the proposal for non-renewal remains unchanged.
   One Member State intervened to state that at national level there were products with far lower rates of use than the representative use applied for and that the applicant should have paid more attention to the selection of the uses when applying for renewal. The same Member State expressed the importance of thiram for some crops and that there could be some possibility for refining the risk assessment if such rates could be considered. However, the Commission reminded Member States that decisions should be taken on the basis of the Good Agricultural Practices (GAPs) applied for.
   Another Member State asked the Commission to carefully consider the implications of a non-renewal on the import and use of treated seed. The Commission indicated that this issue had been dealt with in other cases (e.g. neonicotinoids) and would also be given thorough consideration in the case of thiram.

Member States were invited to come forward with any final comments or risk assessments that could demonstrate acceptable risk to birds and mammals from the use as seed treatment.

e. Bifenazate (short update only)
The Commission informed about the comments received and the additional calculations made available by RMS SE. Member States were invited to send in their views by 17 November 2017.

f. Bentazone (short update only)
The Commission explained the changes to revision 5 of the proposal. The Commission intends to submit the draft for renewal of approval for vote in December.

g. Mecoprop-P
The Commission proposed to not renew the approval of Mecoprop-P. The Commission provided a summary of the comments received from the Member States and the comments of the applicant to the Renewal Report. The unacceptable risk to workers is of critical concern, driving the file toward a non-renewal. The documents provided by the applicant were made available to the Member States. Member States were asked to submit their comments by 20 October 2017.

h. Carfentrazone-ethyl
The matter had been referred back to section A of the agenda, as the Commission-internal consultation was not fully concluded. While several Member States already marked their agreement with a renewal of the substance, there are a significant number of them which are reluctant, either due to the intrinsic risk profile of the substance and/or to the restrictive approach taken by the Commission services as regards the recourse to requests for confirmatory information from applicants.

i. Laminarin
The Commission brought the attention to the concerns expressed in the EFSA conclusion. Member States were invited to send in their views on the draft renewal report by 27 October 2017.

j. Propyzamide
No discussion

k. Silthiofam
No discussion

l. Pymetrozine (short update only)
Points l and m were discussed together.

m. Isoxaflutole (short update only)
Points l and m were discussed together.
Member States were reminded that both of these substances are considered endocrine disrupting chemicals according to the interim criteria laid down in Regulation (EC) No 1107/2009. Assessments of negligible exposure and under the Article 4.7 derogation were either completed or ongoing.
As the approval criteria detailed in Annex II point 3.6.5 require that a judgement is made on whether the substance can be used such that exposure

to humans is considered negligible, this aspect should be decided upon, taking into account the assessments carried out.
The Commission was therefore considering next steps with this in mind and once the internal procedure was more advanced would present to Member States a draft.
Two Member States took the floor to explain that they would either vote against or abstain from any draft concerning renewal due to the issues identified for leaching of metabolites to groundwater.

n. Clonostachys rosea J1446
No draft review report was presented yet. The Commission informed the Member States that it has approached EFSA with some questions for clarification about the EFSA Conclusion. Member States were invited to send in their views by 17 November 2017.

o. Forchlorfenuron
The Commission presented a draft renewal report and draft Regulation proposing the renewal of approval of the substance. Member States were invited to send in their comments by 17 November 2017.

p. Mepanipyrim
The Commission presented a draft renewal report and draft Regulation proposing the non-renewal of approval of the substance. Member States were invited to send in their comments by 27 October 2017.

q. Acetamiprid (amended reference values in the RR to be noted)
The Commission had uploaded a draft renewal report and draft Regulation proposing the renewal of approval of the substance, including the new reference values. Member States agreed to send the mandate to EFSA to provide a reasoned opinion on the existing MRLs which might lead to consumer intake concerns.
The Commission intends to submit the draft for renewal of approval for vote in December.

A.04 Confirmatory Data:

1. Bifenthrin
As it seems unfeasible to mitigate in practise the remaining ecotoxicological risk (recolonization of non-target arthropods in field and bioaccumulation/ biomagnification in aquatic and terrestrial foodchain), the Commission is proposing a restriction to use in greenhouse only. That option seems well supported by Member States. The draft has been internally agreed and has already been notified to the World Trade Organisation (WTO) under the TBT system (Technical Barriers to Trade). The commenting time by Third Countries is expiring on 12 November 2017, which is in time for a vote in the Committee of December 2017.

2. Thiamethoxam (short update only)
Points A.04.02-04 were discussed together.

3. Clothianidin (short update only)
Points A.04.02-04 were discussed together.

4. Imidacloprid (short update only)
   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.
   The legal drafting of the three draft Regulations was finalised and the drafts were notified to the World Trade Organization. Deadline for commenting under these TBT notifications was 3 October 2017. 3 comments were received to which the replies are under preparation.
   The Commission informed the Standing Committee of further comments received from grower associations. A representative part of these letters had been made available on CIRCABC. Already more than 100 letters from grower associations on this subject have been replied to in 2017.
   Further feedback from Member States was made available on CIRCABC as well as one comment from one of the applicants. Also letters received from NGOs were made available on CIRCABC.
   Some Member States repeated their concern on the use of the non-adopted Bee Guidance Document. One Member State underlined that the consequences of all actions need to be considered and that the current proposals might not achieve their environmental goals.
   The Commission will reflect on the next steps and invited Member States to send in their views on the draft Regulations by 17 November 2017.

5. Cyflumetofen (discussion only)
   The Commission brought to the attention of the Committee the new information sent in by the applicant and evaluated by the Netherlands in addition to the confirmatory data. Member States were asked to provide their opinion by 27 October on the way to close the file, with consideration of these additional data or not. If not, they were also invited to propose options on how to consider the outstanding study.

6. Malathion
   Due to the identified high risk to birds, the Commission proposed a restriction to use in greenhouses only. As some uncertainties from metabolites that could occur through processing have been identified, it is suggested that this matter is dealt with at authorisation level, where Member States may request further toxicological information should such uses be intended. The draft seemed supported generally by Member States. However, the internal consultation took more time than expected and is not finalised to date. Afterwards the measure will also have to be notified to WTO under the TBT procedure, which excludes any vote in December 2017. It is likely this vote could take place in January 2018 or, in the worst case, in March 2018.

7. Dithianon
   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 by 27 October.

8. Tri-allate
   One important problem is the relevance or not of one soil metabolite (diisopropylamine - DIPA), which occurs at higher concentrations in groundwater and is suspected to be a precursor to nitrosamines in the case of water treatment. DIPA is of low acute toxicity and has not been classified by ECHA as toxic.

RMS UK does not consider this metabolite to be relevant but EFSA, in the absence of the raw data, judged the evidence too weak to share that conclusion. Furthermore, the residue definition for risk assessment is provisional and the Commission is reflecting on a mandate to EFSA as to define an agreed residue definition. The applicants had submitted several position papers which were tabled (list of ongoing studies as regards toxicology and ecotoxicology of DIPA, monitoring results in IT showing only exceptionally a leaching of DIPA above 0.1 µg/l, impact of groundwater treatment on formation of nitrosamines from DIPA which they consider negligible). Other ecotox issues seem unproblematic (risk to fish-eating mammals and earthworms).

9. Eugenol
   The Commission did not draft a review report yet and only one Member State already commented that the presence of the genotoxic carcinogen methyleugenol is alarming. That compound occurs as an impurity (in concentrations on which there seem to be some doubts) and, in the absence of a plant metabolism study, it cannot be ruled out that it also occurs as a degradation product in or on treated crops. Member States were invited to reflect on the acceptability of this compound of concern, taking into account that it is a natural component in food (herbs) and in several essential oils (clove oil). Comments are expected by 27 October 2017. The profile of the other substances (thymol and geraniol) seems less problematic.

10. Geraniol
    See above sub Pt. A 04.09

11. Thymol
    See above sub Pt. A 04.09

12. Terbuthylazine
    The Commission reminded Member States of the pertinent issues. With regard to the points related to the specification and impurities, this could be addressed by lowering the limits of 2 relevant impurities in the approval to ensure the substance overall does not need to be labelled as carcinogenic category 2.
    With regard to groundwater, it was highlighted that terbuthylazine has a highly complex groundwater profile with a number of (non-toxicologically relevant) metabolites predicted to occur in groundwater above the regulatory threshold of 0.1 µg/L.
    The EFSA Conclusion highlights several concerns in relation to leaching of metabolites and also possible consumer risk for infants from exposure to them. The Commission was considering whether it was possible to allow Member States to consider the risk to groundwater when looking at authorisations, however, welcomed views from Member States on the way forward before making any formal proposal.

13. Iprovalicarb
    The Commission tabled a revised review report which reflects the views of EFSA and commenting Member States, concluding that it is unlikely that soil metabolite PMPA (paramethyl-phenethylamine) is genotoxic. One Member State raised an issue which however is not part of the requested confirmatory data and is of a more general nature, namely the application of the Guidance Document on Metabolites in Groundwater, in the case of a draft for classification of the parent compound.

The Commission recalled that the Guidance Document explicitly refers to substances which are classified according to the harmonised system only and is therefore not relevant in this case. The Commission believes that the revised review report can remain unchanged and may be noted in the December 2017 meeting.

14. Metazachlor
In the recent past, the classification as carcinogen category 2 has been confirmed, implying that confirmatory information as regards the relevance of metabolites must be submitted. The submitted data shows that the metabolites of metazachlor leach above 0.1 µg/l in all scenarios. EFSA has come to the conclusion that metabolites M09 and M11 are to be considered relevant. Moreover EFSA states that, although of good quality, the monitoring data provided are insufficient to overrule the FOCUS modelling. The applicants commented that EFSA did not address adequately the mandate and applied its own criteria (in the absence of agreed guidance). It disagrees with the rejection of several monitoring results by EFSA. On the basis of the review however, the Commission must conclude that the two above metabolites leach in all scenarios and that the monitoring data failed to overrule that fact. As a consequence, it seems logical to propose, at this stage of debates, a withdrawal of the approval of the substance. Comments by the applicants will be tabled for further discussion.

15. Pyrethrins
Following up on the outcomes of the assessment of several confirmatory studies, the Commission informed Member States about the draft to launch an Article 21 review to allow submission of information necessary to conclude the toxicological assessment of metabolites. Member States were invited to comment on the proposed review by 27 October 2017.

16. Acetic acid
The Committee took note of revision 5 of the draft review report.

17. Picloram
Confirmatory information has been requested on the adequacy of the analytical method applied in residue trials and a soil photolysis study to confirm picloram degradation. In both cases, EFSA and commenting Member States believe the issues to be well addressed. As a consequence, it is proposed to take note of the revised review report, as tabled, at the December 2017 meeting.

18. Chlorsulfuron
The Commission intended to draft a revised review report closing the current request for confirmatory information as regards groundwater metabolites. Indeed, it seemed that that request became void as the compound has finally not been classified as a carcinogen category 2. However, it would appear that the non-classification might be due to the non-availability of the pertinent toxicological data at ECHA level. For the sake of completeness, the Commission would like to understand from the competent national authority for which reasons the mammalian toxicity part of the data package has not been forwarded to the competent ECHA experts.

19. Triazine amine (common metabolite)
Member States were informed that there are 5 sulfonylurea substances that share the common metabolite triazine amine, which may be present as a residue or in groundwater. The genotoxic potential of this metabolite could not be concluded

during the renewal of the substances based on the information available at the time of each evaluation.
The first of these substances to undergo renewal and where a confirmatory requirement was set to confirm that the metabolite is not genotoxic was metsulfuron-methyl. For that substance the applicants submitted information which was evaluated by Slovenia and reviewed by MS and EFSA. A commenting period followed and EFSA produced a Technical Report summarising the outcomes. EFSA concluded that the genotoxic potential of triazine amine could still not be concluded.
In the meantime the applicants for iodosulfuron and prosulfuron, where confirmatory information is to be submitted, asked the Commission for an extended deadline in order to provide a single submission on behalf of a task force, using all available data to resolve this issue. The Commission was considering the proposals and will decide how to proceed. Applicants had been advised to ensure that a submission was made by the appropriate deadline in any case.

20. AOB
    No item 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:
   None. No discussion took place.
2. Exchange of view on EFSA conclusions:
   a. Fenazaquin
      The Commission summarised comments received from the Member States and proposed a possible way forward. The Member States were asked to provide their comments on the proposed amendment of the conditions of approval of fenazaquin by 27 October 2017.
3. Draft Review/Renewal Reports and Regulations for discussion:
   a. Penflufen (no news)
      The Commission informed that an inter-service consultation was on-going and that Member States will be asked for their opinion on penflufen during the December Committee.

A.07 Basic substances:

1. Pilot projects: state of play
2. New dossiers received (only for information)
   a. Milk
      The applicant is Basic-Eco-Logique from France. The intended use is as a fungicide in a variety of crops.

b. Sodium hypochlorite
The applicant is Laboratoires A.C.I. from France. The intended use is as seed treatment for vegetable seeds and disinfectant in the cultivation of mushrooms.

3. Exchange of views on EFSA Technical Reports

a. Talc
The Commission underlined that EFSA outcomes on the operator and groundwater assessment would allow for approval as basic substance of Talc E553B given the respect of specifications as food additive.

b. Vinegar
The Commission gave a first view on the EFSA technical report on vinegar. Points raised by EFSA include the concern for inhalation of acetic acid in vinegar, leading to a potential exceedance of the Acceptable Operator Exposure Concentration, and the contamination of groundwater. There was insufficient data to conclude on the effects on the environment.

4. Draft Review Reports for discussion:

a. *Saponaria officinalis* root extract
The Commission presented a draft review report to support the proposal for approval of *Saponaria officinalis* root extract. However, the Commission informed the Member States that information from the literature indicated the presence of a potentially toxic compound present in the root. The Commission will follow-up on this with EFSA. Member States were invited to send in their comments by 17 November 2017.

b. Talc
The Commission presented a draft review report to support the draft for approval of talc E 553B as basic substance. Member States were invited to send in their comments by 27 October 2017.

c. Honey from rhododendron
The Commission informed Member States of an ongoing discussion with the applicant on the review report regarding the non-approval of this substance as a basic substance. The e-mail exchanges were made available on CIRCABC.
The Commission informed the Member States of a French decree in La Réunion prohibiting the sale of honey comb when local Rhododendron varieties are flowering. Honey from the *Rhododendron ferrugineum* variety is for sale in Austria. The grayanotoxin content in this honey is not known. The feedback from Member States is made available on CIRCABC.
The Commission informed Italy of animal experiments by the applicant which do not seem to be conducted by qualified personnel and which seem to be conducted without prior authorisation by the competent authorities of Italy.
Member States were invited to indicate if honey from rhododendron (and if applicable its content of grayanotoxin) is sold on their territory and were invited to notify, if applicable, any national law regulating the sale of this honey by 17 November 2017.

A.08 Exchange of views on Guidance Documents:

1. Template to be used for Assessment Reports (SANCO/12592/2012 Rev. 1, for discussion and possible noting)
   The Commission presented the final version of the template revised to address both the evaluation under Regulation (EC) No 1107/2009 and the hazard identification under Regulation (EC) No 1272/2008. The last changes introduced to address the German comments received were highlighted.
   The template was unanimously noted by the Committee, with an application for new active substances dossiers submitted from 6 October onwards. It will be published on the Commission website.

2. Guidance Document on Data Protection (SANCO/12576/2012 Rev. 2.2, no discussion)
   This Guidance Document was not discussed as the internal discussion in the Commission is not finalised.

3. Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010 Rev. 10, to be noted)
   This Guidance Document was not discussed as the internal discussion in the Commission is not finalised.

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, for discussion)
   The Commission informed the Committee of a new revision of the template for dRR, proposed by the PAI group. Comments were requested by 17 November.

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 for discussion)
   The Commission presented the revised terms of reference, highlighting the changes made to address the comments received since the July meeting of the Committee. The Commission stressed the need to involve EFSA for the discussions related to active substances procedures. However it considers that the PAI group is the relevant forum under the Standing Committee to address procedural issues, other than the peer review procedure linked with active substance dossiers. Comments from Member States were requested by 17 November.

6. Report from the Danish EPA workshop on data requirements for acute inhalation toxicity testing – follow-up
   The Commission informed the Committee that a follow-up discussion is envisaged in a workshop organised on the harmonisation of risk assessment in the area of toxicology in France in Spring 2018 (see point A.32).

7. Guidance document on the Evaluation Efficiency of Residue Analytical Methods (SANTE/10632/2017, for discussion)
   The Commission informed the Committee about the revision of the Guidance Document on the Extraction Efficiency for Residue Analysis. This revision is also discussed in the Residue section of the Committee. It will be noted there. Comments were requested by 6 November.

8. Guidance document on the establishment of the residue definition for dietary risk assessment (SANTE/11644/2017, to be noted)

At the PAFF Committee on Residues held on 21 September 2017, the Commission prepared a cover note for endorsement of the guidance document. In terms of implementation schedule, it had proposed a deferred application of 18 months to ensure that all relevant parties comply with the new requirements. Member States were invited to submit comments by 30 September 2017.

At the current meeting, the Commission outlined the positions received from several Member States. Only one Member State has no objections and is in favour of the implementation schedule. Moreover, it proposed to anticipate the applicability of specific parts of the guidance document, which would lead to benefits such as reducing animal testing.

Other Member States raised concerns on the complexity of the guidance document and the need for training. Furthermore, the involvement of toxicological experts is needed to address those situations that would require expert judgement when using the new tools. It was also acknowledged that the overall workload would be increased at RMS level.

The Commission informed Member States that EFSA had made a commitment at the last PAFF to provide the necessary training to enable applicants and national competent authorities to use the new tools reported in the Guidance document.

A Member State was concerned on the impact that the future residue definitions, which would include an increased number of metabolites, would have on the transposition of Codex limits. Two Member States questioned the benefits resulting from the strengthening of the residue definition. These Member States suggested that before endorsing the guidance document, an impact assessment should be carried out to estimate the additional workload and the actual consequences in relation to its application.

The Commission stressed that neither Member States nor EFSA should make use of the Guidance Document before it becomes applicable.

Member States were invited to submit comments on the guidance document and on the appropriate implementation schedule by 31 October 2017.

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

67 notifications were submitted by Belgium concerning the amendment of authorisations of products containing glyphosate.

55 notifications were submitted by Belgium concerning withdrawals of products containing POE tallowamine.

One notification was submitted by Hungary concerning a product containing diflubenzuron.

11 notifications were submitted by Portugal concerning the withdrawal of authorisations of products concerning chlorpyrifos-methyl.

1 notification was submitted by Portugal concerning the amendment of an authorisation of a product concerning chlopyrifos-methyl.

The Committee took note of the notifications sent by Belgium, Hungary and Portugal.

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

No notification submitted.

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

1. Notifications (to be noted)

- Dimethoate (Belgium)
- Zinc phosphide (Czech Republic)
- Spinosad (Czech Republic)
- Copper hydroxide (Germany)
- Lime sulphur (calcium polysulphid) (Germany)
- Lambda-Cyhalothrin (Germany)
- Hexythiazox (Germany)
- Spinosad (Greece)
- Abamectin (aka avermectin) (Greece)
- Spirotetramat (Greece)
- Bifenazate (Greece)
- Tebufenpyrad (Greece)
- Chloropicrin (Greece)
- Fosetyl (Greece)
- Napropamide (Greece)
- Mepiquat (Greece)
- Sodium silver thiosulphate (Latvia)
- Chloropicrin (Malta)
- Spinosad (Netherlands)
- Deltamethrin (Portugal)
- Pyrethrins (Portugal)
- Paclobutrazol (Portugal)
- Azoxystrobin, Difenoconazole (Portugal)
- 1,3-Dichloropropene (Portugal)
- Spinetoram (Portugal)
- Spiromesifen (Portugal)
- Imidacloprid (Romania)
- Beta-Cyfluthrin, Clothianidin (Romania)
- Flonicamid (IKI-220) (Slovenia)
- Bifenazate (Slovenia)
- Ethephon, Fosetyl, Spirotetramat (Spain)
- (Z,E)-9,12-Tetradecadien-1-yl acetate (Spain)
- Thiram (Spain)
- Cyantraniliprole (Spain)
- Fluopyram (Spain)
- Picoxystrobin (Spain)
- Mepiquat (Spain)
- Spirotetramat (Spain)
- Spirodiclofen (Spain)
- Thidiazuron (Spain)
- Ethephon (Spain)
- Fosetyl (Spain)
- Spinetoram (Spain)
- Gibberellic acid (Spain)

- Copper compounds, Mancozeb (Spain)
- Spinosad (Spain)
- Thiacloprid (Sweden)
- Copper oxychloride (United Kingdom)
- Cyantraniliprole (United Kingdom)

The Committee took note of the notifications submitted by Belgium, Czech Republic, Germany, Greece, Latvia, Malta, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden and 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.

2. Update of the Working document on emergency authorisations according to Article 53 (for information)
   The Commission informed that an update of the working document may become necessary, depending on the outcome of the analysis mentioned under agenda point A.11.3.

3. Mandate to EFSA under Article 53(2) in relation with emergency authorisations granted in 2017 for products containing imidacloprid, clothianidin, or thiamethoxam
   The Commission informed the Member States about a mandate to EFSA to examine the emergency authorisations repeatedly granted by some Member States since the restrictions had been adopted in 2013. It concerns the emergency authorisations for maize, sunflower and oil seed rapes for products containing the restricted neonicotinoids. Seven Member States have annually granted since 2014 such Art. 53 authorisations.
   EFSA is requested to assess whether the repeated use of emergency authorisations was necessary because of a danger which could not be contained by any other reasonable means.

The Commission informed that EFSA will send a reporting table to all Member States concerned by mid-October to update their notifications according to the insecticide protocols for Art. 4(7) evaluations (published by EFSA on 5 April 2017). The Commission emphasised the need for all Member States concerned to reply timely to EFSA.
Two Member States indicated that EFSA is not able to judge local agronomic practices and the availability of alternatives in individual Member States and consider this a Member State competence. The Commission indicated that Article 53(2) of Regulation (EU) No 1107/2009 explicitly mentions that the Commission may ask EFSA for scientific or technical assistance.

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

Due to technical problems for a remote connection, no oral update was given during the conference. A presentation had been uploaded on CIRCABC which covered the following topics:

- Update on Pesticide Steering Network
- Issues related to the peer-review process
- List of endpoints in the area of residues
- Panel on Plant Protection Products and their Residues and planned events
- EFSA contribution to REFIT of Regulations (EC) No 1107/2009 and 396/2005

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

The Commission informed the meeting about a package of actions planned for 10 October, date on which the report on national action plans to be transmitted to Parliament and Council will be adopted by the Commission. The Commission proposed discussion in the AGRI-Council meeting of 6 November but it has still to be confirmed. Another important report including an overview of audit outcomes will be published on the same date. The Commission will discuss both reports in the next meeting of the SUD experts group of 18 October. On 10 October, the Commission plans also to adopt the Strategic Guidance document on monitoring of impacts of pesticides in compliance with Article 7 of the SUD. Finally, a webportal on the SUD and in particular on IPM will be launched on the same date. Member States were invited to liaise with concerned colleagues for proper follow up.

A.14 Reports from working groups.

1. Plant Protection Products Application Management System (PPPAMS)
   The Committee informed that there was no significant progress since the July meeting but that work would resume on the next release. Information would be disseminated to relevant stakeholders ahead of the release. Member States would be contacted before the release to perform testing.

2. Post Approvals Issues group (PAI)
   Belgium gave some feedback about the last meeting of the PAI group. The group discussed the comments received form the Standing Committee concerning the draft terms of reference. The group furthermore discussed the issues which might arise if the confirmatory data assessment is not finalised in time before the renewal process starts. The group will analyse the situation and inform the Commission, if necessary.

The discussion on the national processes under article 43 was continued. The experts furthermore discussed recent developments under the draft guidance document on data protection, the guidance document on zonal authorisation & mutual recognition as well as procedural questions concerning the application for low-risk plant protection products.

3. Sustainable plant protection experts group Dutch proposal (no meeting)
   The Commission informed that the next meeting of the working group has been postponed to end of November. A precise date will be given as soon as possible. The Commission thanked Member States who have already addressed the questions for the interim report and solicited the missing ones to do so as soon as possible to allow completion of the interim report.
4. Working group on Biopesticides (no meeting)
5. Working group on Seed Treatments (no meeting)
6. Working Group on Co-formulants
   Discussion postponed.
7. Working Group on low-risk criteria
   The Commission informed that the next meeting will be held on 18 November.

A.15 Organisation for Economic Co-operation and Development (OECD).

No news since last meeting.

A.16 Court cases.

New court case: T-476/17 Arysta LifeScience v. Commission – Application for the annulment of Commission Implementing Regulation (EU) 2017/855 on diflubenzuron.
The Commission informed the Committee of this new court case.

A.17 Endocrine Disruptors.

1. State of play: ED-criteria and development of EFSA/ECHA guidance document
   The Commission informed that on 4 October the European Parliament (EP) opposed to the criteria voted by this Standing Committee on 4 July with 389 votes in favour, 235 against and 70 abstentions. The EP believes that the Commission has exceeded its powers with the provision on the insect growth regulators, which had been added on request of Member States during the negotiations. The scrutiny of the ED-criteria for biocides, identical in content to the PPP-criteria and adopted on 4 September, is still on-going until 4 November with possibility of extension for two additional months.
   One Member State wondered if the Commission can indicate which options are now possible; the Commission indicated that reflections are currently ongoing.
   The Commission informed that the work on the joint guidance document to implement the ED-criteria, being prepared jointly by EFSA and ECHA and applicable to both pesticides and biocides, is progressing well. A public consultation could be launched end of November. However, due to the opposition of the EP to the ED-criteria for PPP, reflection on the process and the next steps is needed.

2. Implementation of the new ED-criteria for the renewal of active substances: Amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties
   This point became obsolete due to the opposition of the European Parliament to the ED-criteria (see above).

3. Implementation of the new ED-criteria new active substances
   This point became obsolete due to the opposition of the European Parliament to the ED-criteria (see above).

A.18 Minor Uses.

The EU Minor Uses Coordination Facility participates in the ongoing Global Minor Uses Summit in Montreal with several presentations (also on behalf of the Commission). All presentations can be found on the Global Minor Use Portal www.gmup.org.
A discussion concerning the long-term funding of the Coordination Facility is on the agenda of the following AGRI-Council. DG Health and Food Safety will send a letter to all Member States very soon, stressing the achievements of the Coordination Facility during the last three years and stressing the importance of a continued funding by Member States. The letter will be made available to the Committee via CIRCABC.

A.19 Interpretation Uses.

1. Scope of Regulation (EC) No 1107/2009:
   a. *Plant strenghteners (request by Lithuania)*
      Lithuania was invited to resubmit this question which will be examined in priority.
   b. *Product Ecobakter-Terra and others, produced by Biofactory (request by Greece)*
      Although the product has mainly fertilising properties, some of the claims indicate the application of the PPP legislation. This is namely the case for the claim on the strengthening of the immunity system of plants against pathogens, frost and drought.
   c. *Garlic oil (request by the Czech Republic)*
      Garlic oil has not been approved for administrative reasons (lack of dossier), while garlic extract has been approved after a scientific assessment. It cannot be a priori excluded that the oil is covered by the current specifications for the extract. However, that is immaterial as the product manufactured is intended for fumigation purposes, a use not authorised for garlic extract, the latter only being limited to granular forms, applied in or on soils. It must therefore be concluded that application of garlic oil for fumigation is not an authorised use.

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.

2. Preparation of Harmonised Classification and Labelling dossiers (CLH dossiers) by Member States – Amending Implementation Regulation 844/2012 in view of the harmonised classification of active substances
   During the Committee meeting of May 2017, the Commission presented a draft Regulation amending Regulation (EU) No 844/2012 concerning the harmonised classification of active substances. The Commission received comments from 4 Member States.
   Taking into account the comments received, the Commission intends to amend its draft and request the RMS to always submit a dossier to ECHA:
   - to propose harmonised classification in case there is no harmonised classification under Regulation (EC) No 1272/2008,
   - to revise or confirm existing harmonised classification.

   The Commission underlined that the requirement for harmonised classification for pesticide substances is set in Article 36(2) of Regulation (EC) No 1272/2008 and the amendment of Regulation (EC) No 844/2012 would not be a new requirement. The act would clarify the timing of the submission of a CLH dossier and would align the harmonised classification process with the assessment of the substance to be renewed.

3. Follow-up of the merging of CLH and xAR templates (discussion only)
   No news since last meeting.

A.21 Glyphosate.

a. State of the dossier
b. 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_glyphosate_paff_meeting_sum_20171005.pdf.

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

No news.

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 gave an update about the workshop held on 12 September with some Member States, stakeholders and the contractor. The main discussion was on the questionnaires for the Member State and stakeholder surveys. The questionnaires are about to be finalised and it is expected that they are launched at the beginning of November together with the open public consultation and the SME survey.

The Commission informed that in addition to the surveys, the Contractor will carry out interviews after the completion of the surveys. Member States were also invited to consider if they would like to participate in one of the focus groups that are to be held after the completion of the surveys. Four focus groups are planned on the topics of
1) *Risk assessment,*
2) *Risk management and decision making,*
3) *PPP Authorisation,*
4) *MRL setting.*

A.24 Exposure of florists to plant protection products from cut flowers.

The Commission informed that further information was submitted by two Member States.
The Commission informed the Member States about key Directives with regard to exposure of workers to hazardous chemicals:

1. Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work
2. Directive 98/24/EC on the protection of the health and safety of workers from risks related to chemical agents at work
3. Directive 2004/37/EC on the protection of workers from the risk related to exposure to carcinogens or mutagens at work.
4. Directive 89/656/EEC on personal protective equipment is likely to be relevant.

One Member State indicated the need for further data to fully understand the situation.
One Member State indicated that a new publication will be available soon and reminded that it already proposed further steps in an earlier communication.
The Commission invited Member States to send in proposals on possible further steps by 17 November 2017.

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

The Commission informed the Member States of the letter it sent in response to the two letters received in which concerns were expressed about the use of pepino mosaic virus by tomato plant propagators.
The Commission informed that four Member States sent in their views in which they expressed to share the concerns. Two Member States proposed a restriction of use of pepino mosaic virus to tomato growers, to be implemented on EU level.
The Commission underlined that the Committee voted in favour of the approval of two isolates in January 2017 and that the approval procedure was finalised. Introducing a restriction of use requires an amendment of the conditions of approval. This can be done through an Article 21 review. Alternatively, the Commission highlighted that the zonal evaluation procedure for product authorisation of the two recently approved isolates is still ongoing and that this is an EU-wide procedure (one zone) which would provide an opportunity for Member States to agree on the necessary measures to address the concerns with regard to the use by tomato plant propagators.
Therefore, the Commission advised Member States to address their concerns and proposals in the commenting phase of this procedure and to discuss the matter in the interzonal steering group if necessary to reach agreement on any conditions that need to be set in the product authorisation.
The Commission expressed that if this does not lead to a satisfactory outcome, it could consider an Article 21 review.
The zonal Rapporteur Member State noted it was aware of the concerns. It confirmed that the zonal evaluation procedure is still ongoing and that there is still a possibility to include measures, if necessary.

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

The Commission has made available a final draft to the Committee recently. The Commission intends to adopt the mandate during the meeting in January 2018.

A.27 2,4-D - Revision of AOEL, ADI and ARfD (Revised review report to be noted).

The Commission tabled a revised review report, including the new toxicological reference values, as well as a slightly modified consumer exposure estimation. This revision is justified by the amendment of the EFSA conclusion (March 2017) as regards 2,4-D. While it is concluded that there is no need to reconsider the approval conditions, at the level of authorisations it must be verified whether parts of the human exposure must not be critically reconsidered (e.g. operator exposure.). The situation is well known, as is the position of the applicant, and in the absence of specific written comments by the Member States, the Commission proposed to note the revised review report in this session of the Committee.
The Committee took note of the revised review report. One Member State was not in agreement and will provide comments in writing after the meeting.

A.28 Protection goals for environmental risk assessment – update on next steps.

The Commission stated that information has been sent by two Member States and invited all other Member States to send information by end of October. One Member State mentioned that a workshop on the topic will take place before the end of October and that they may send additional information after this workshop.

A.29 Pest management changes after neonicotinoid and fipronil restrictions: results from a survey (Article publicly available).

The results of the survey were presented by the Commission (DG JRC).

A.30 Initial information concerning Brexit.

The Commission informed the Committee that, pre-Brexit meetings will be organised with the remaining 27 Member States. These meetings are intended for organising a smooth handover of tasks for which the United Kingdom is currently in charge, but for which it can be expected that they will not be accomplished by the date of the Brexit.
For plant protection products a substantial part of that work has already been accomplished by the recent modifications of the 4th renewal programme ("AIR4").
Remaining open points (e.g. on confirmatory information or new active substances) will be discussed in pre-Brexit meetings.
The United Kingdom raised its dissatisfaction about this approach as it shall be considered a full Member State until the date of Brexit.

A.31 Scientific publications and information submitted by stakeholders.

All information received from stakeholders ahead of the meeting was made available to the Committee.

A.32 Date of next meeting.

The meeting was provisionally confirmed for 12-13 December 2017.

B.01 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 Rev2)

Reasons for abstention/negative opinion:
Need for a review of the approval as 8-hydroxyquinoline meets the cut-off criteria.

Vote taken: Favourable opinion.

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 iprodione 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 Renewal Report SANTE/10627/2017 Rev1).

Reasons for abstention/negative opinion:
Period of grace too short to recollect products from retail chain and users.

Vote taken: Favourable opinion.

B.03 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 flonicamid (IKI-220), metalaxyl, penoxsulam and proquinazid.

Reasons for abstention/negative opinion:
- Extension period too long.
- Approval of substances with different risk profiles should not be extended together in one decision.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of paprika extract (capsanthin, capsorubin E 160c) as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Draft Review Report Doc. SANTE/10068/2017)

No discussion.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of *Achillea millefolium* L. as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Draft Review Report Doc. SANTE/10142/2017).

Reasons for abstention/negative opinion:
Substance should be approved as basic substance.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of beer as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Draft Review Report Doc. SANTE/11038/2017 Rev1).

No discussion.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of potassium sorbate as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Draft Review Report Doc. SANTE/11031/2017).

No discussion.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of mustard seeds powder as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Draft Review Report Doc. SANTE/11309/2017).

No discussion.

Vote taken: Favourable opinion.

M.01 Workshop on harmonisation of risk assessment for Plant Protection Products in the area of toxicology - (Paris, 2018).

Member States were reminded that the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) will organise a follow up workshop in March 2018 to those held in Berlin and Vienna in 2014 and 2015 respectively. An invitation and agenda would be circulated in due course. As in previous events the workshop would include participation of Member States, EFSA, Commission and industry.