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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals* – Legislation
21 - 22 MARCH 2019

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SUMMARY REPORT

A.01 Summary Report of previous meetings:

Member States were informed that the summary reports from previous meetings were published, except for the January meeting for which the report is finalised and sent for publication.

A.02 New active substances:

1. *New admissible dossiers to be noted:*

The Committee took note of the dossier for the new active substance Inpyrfluxam (S-2399), for which the Netherlands are Rapporteur Member State. Admissibility for this fungicide was confirmed on 8 February 2019.

A dossier for the new active substance Trichoderma atroviride AT10 had been submitted but the Committee was not yet in condition to take note as not all Member States had received the information.

2. *Exchange of views on new European Food Safety Authority (EFSA) conclusions:*

a) 1,3 Dichloropropene

The Commission summarised the EFSA Conclusion and informed the Member States about the comments received from the applicant. The Member States were invited to submit their comments and opinion about the way forward by 23 April.

b) Napropamide-M

The Commission summarised the EFSA Conclusion and informed the Member States about the comments received from the applicant. The Member States were invited to submit their comments and opinion about the way forward by 23 April.

3. *Draft Review/Renewal Reports for discussion:*

a) Florpyroaxyfen benzyl

The Commission presented the draft review report and draft implementing Regulation and informed the Member States about the comments received from 4 Member States expressing their preference for an approval, with a request for confirmatory information as regards the endocrine disrupting potential. The Commission invited Member States to submit comments on the draft documents by 5 April 2019 and announced its intention to ask the Committee for an opinion in the next meeting.

b) Lavandulyl senecionate

The Commission summarised the EFSA Conclusion and informed the Member States about the comments received from the applicant. The Member States were invited to submit their comments by 23 April 2019.

A.03 Renewal of approval:

1. *Annex I Renewal Projects: State of play*

No news to discuss.

2. *Exchange of view on EFSA conclusions/EFSA scientific reports:*

No news to discuss.

3. *Draft Review/Renewal Reports for discussion:*

a) Bromoxynil

The Commission provided a short update. A draft renewal report was not yet available given the ongoing discussions on the non-dietary exposure assessment that is the key area relevant for decision-making, in particular the different outcome for resident exposure using the EFSA guidance compared to the use of the German model that was applicable at the time of dossier submission. The Commission indicated that a non-renewal of approval was a possible option but that some further time was needed to further investigate certain aspects, including the use of the Benchmark Dose Approach (BMD).

b) Flumioxazin

The Commission updated the Member States regarding a recent opinion adopted by RAC on the classification of this substance, and indicated that it is reflecting on the way forward.

c) Clodinafop

The Commission updated Member States on comments received since the meeting of the Committee in January. The rapporteur Member State had expressed its disagreement with the setting of the AOEL once again. Two Member States had expressed their concern that no safe use was possible, in particular due to the exposure assessment for workers and residents.

The applicant submitted new information related to the non-dietary assessment, indicating that further mitigation or refinements are possible that could have already been taken into account. The Commission indicated that it was considering sending a mandate to EFSA to further explore such measures.

The rapporteur Member State again indicated that it believed the AOEL is inappropriately set. Given this position, the Commission invited Member States to

consider the position of the rapporteur Member State and the last comments and to submit their reactions by 5 April 2019.

d) Fenamiphos

Four Member States had expressed, based on the EFSA Conclusion, concerns about the substance.

The Commission explained that a draft renewal report was not yet available. The Commission indicated that after considering the consumer risk profile, in any case edible uses would need to be excluded from a potential renewal of approval. A consideration of the remaining uses (non-edible crops grown in greenhouses) was underway. Concerning the high potential for groundwater contamination by metabolites of fenamiphos, as indicated in the FOCUS modelling, the Commission asked Member States to consider the Greek monitoring data available and mentioned in the Conclusion. Several Member States had provided concerns about the use of such monitoring to support an approval. Some other issues relevant for the non-edible uses also needed further consideration. The Commission invited Member States to submit further comments by 5 April 2019.

e) Metalaxyl-M

The Commission reminded Member States that the key issues that need to be solved for a possible renewal of the approval of metalaxyl-M are the risk of groundwater contamination and the risk to birds and mammals for the seed treatment use. Two Member States highlighted the importance of the seed treatment use and cautioned against restrictions forbidding the use as a seed treatment. Another Member State asked whether seeds treated with metalaxyl-M could be limited to greenhouses only. The Commission explained that a decision needed to be taken based on the representative use but that this solution could be considered if the crops were indeed grown in greenhouses. The Commission outlined arguments to address the risk to groundwater and highlighted that in the event of a restricted approval the applicant could submit more data under Article 7 requesting an amendment of the conditions of approval, addressing the issues identified. One Member State said it would need to consider the groundwater argumentation further. The Commission invited Member States to submit further comments by 5 April 2019.

f) Fosetyl

The Commission informed the Member States about the outcome of the discussion on this substance in the Peer Review Expert Meeting 190 on Toxicology. At this meeting experts decided that there is no need to set an ARfD and AAOEL for this substance, consequently EFSA revised its conclusion.

g) Etoxazole

The Commission informed the Member States about the comments received from seven Member States expressing their preference on which way forward should be followed for this substance. The Commission strongly encouraged the Member States again to communicate their preferences on the way forward by 5 April 2019, in order to prepare the documents for the next meeting.

h) Alpha Cypermethrin

The Commission informed the Member States about the comments received from the applicant and from six Member States supporting the draft of the Commission. The Commission explained that the draft renewal report had been revised to include on request of Member States two requirements for confirmatory information. The Commission invited Member States to submit further comments by 23 April 2019.

i) Cypermethrin

The Commission informed the Member States about the comments received from nine Member States so far. The views are diverse. The suggestion of the Commission presented in January (renewal with restriction to autumn/winter use while drift reduction would need to exceed 95%) was not supported.

The Commission discussed this active substance also in combination with point A.09. The Commission asked the Member States to comment on whether they would support a renewal where mandatory risk mitigation requirements are set in the implementing Regulation to achieve an objective of exposure reduction to aquatic organisms, off-field arthropods and bees so that safe use is attained (i.e. a drift reduction exceeding 95% and avoidance of use when bees forage). The toolbox to achieve this objective would stay at the discretion of the Member States in order to allow for different ways of implementation, but examples of relevant risk reduction measures (e.g. “75% drift reduction nozzles, combined with a 20 meters buffer zone and a vegetated filter strip or any other combination achieving the same exposure reduction”) could be mentioned in the review report and the draft implementing Regulation. The Commission invited Member States to submit their comments by 5 April 2019.

j) Beta cyfluthrin

The discussion was postponed. The Commission informed that so far comments from two Member States had been received. The Commission invited Member States to submit comments by 5 April 2019.

k) *Verticillium albo-atrum*

The Commission summarised the EFSA Conclusion, informed the Member States about the comments received from the applicant, and presented the draft renewal report. The Commission invited Member States to submit their comments by 5 April 2019.

l) *Pseudomonas chloroaphis* MA 342

The Commission summarised the status of the dossier, i.e. a pending draft implementing measure not to renew the approval. The Commission invited Member States to submit their views on the way forward by 23 April 2019.

m) Bifenazate

The Commission summarised the status of the dossier, i.e. a pending draft implementing measure not to renew the approval. The Commission invited Member States to submit their views on the way forward by 23 April 2019.

n) Clopyralid

The Commission informed the Member States about the comments received from four Member States as well as from farmers' associations urging the Commission to renew the approval of the substance.

The Commission considered that certain clarifications of the EFSA Conclusion by EFSA and the Rapporteur Member State (RMS) were needed as regards the residue trials. The RMS and EFSA confirmed that they will work together to clarify the remaining issue. Based on these results, the Commission will prepare a draft implementing measure. The Commission invited Member States to submit their comments by 5 April 2019.

o) Thiachloprid

The Commission summarised the EFSA Conclusion and informed the Member States about the comments received from the applicant. The applicant proposed risk mitigation measures to solve the critical area of concern as regards the exceedance of the drinking water limit by 3 relevant groundwater metabolites. However, these had not been assessed by the rapporteur Member State nor by EFSA. No Member State proposed any risk mitigation measures during the evaluation process nor during the meeting. One Member State expressed its disagreement with the proposed risk mitigation measures by the applicant. The Commission invited Member States to submit comment by 5 April 2019.

p) Assessment of ED potential in accordance with Commission Regulation (EU) No 2018/605, according to Commission Regulation (EU) No 2018/1659 amending Commission Implementing Regulation (EU) No 844/2012

No news to discuss.

The Commission also summarised the status of discussions concerning the renewal of approval of cyazofamid and proposed a new possible way forward. The Commission encouraged the Member States to communicate their preferences on the way forward by 5 April 2019 and announced its intention to prepare a draft implementing measure for the next meeting.

A.04 Confirmatory Information:

1. *General update (no news)*

No news to discuss.

2. *Metazachlor (amended review report to take note)*

The Commission reminded that the renewal application process and the respective assessment of metazachlor is ongoing and that this assessment would allow for a definitive decision to be taken on the substance; new information concerning groundwater exposure submitted for the renewal would be taken into account, and would allow for a final fully informed decision.

Member States took note of an updated review report for metazachlor following the assessment of confirmatory information, except for five Member States, who did not endorse the updated review report since they had significant concerns about the potential for contamination of groundwater with relevant metabolites:

One Member State indicated that metazachlor was detected in national monitoring schemes and that the possibility for relevant metabolites to also contaminate groundwater could not be excluded.

One Member State had concerns about the impact of water treatment processes on metabolites that may be present in groundwater extracted for drinking water purposes and would require more data in this area.

One Member State considered that withdrawal of approval was justified given that M09 and M11 are predicted to occur above 0.1 µg/L according to FOCUS modelling. The same Member State highlighted that metazachlor is an important substance for certain vegetables and oilseed rape.

Two Member State had general concerns about the potential for leaching of the relevant metabolites into groundwater.

3. ***Ipconazole (short update)***

The Commission informed that it was reflecting on the comments raised in the previous meeting as regards the classification of the active substance as toxic for reproduction category 1B and the appropriateness to initiate a review under Article 21 of Regulation (EC) No 1107/2009.

4. ***Spiroxamine***

The Commission summarised the four areas covered by the request for confirmatory information for Spiroxamine. One of the data requirements remains open due to the lack of guidance. As regards the other areas, some were addressed and do not raise further concerns, but others would need to be further discussed by EFSA experts, notably the risk to aquatic organisms. Therefore the Commission proposed to send a mandate to EFSA accordingly. The outcome of the process will need to be considered during the renewal process for which an application had been received in December 2018.

5. ***Dithianon (short update)***

The Commission informed that discussions between the RMS and EFSA are still ongoing.

6. ***Triazole derived metabolites (TDMs) (short update)***

Member States were informed that an analysis was being undertaken, taking into account comments received from the Triazole Derived Metabolite Group (TDMG) and from Member States.

Two Member States provided comments and considered that there is no risk to consumers from exposure to the metabolites; one however highlighted concerns for epoxiconazole and fenbuconazole. In response the Commission pointed out that the renewal process for epoxiconazole was advancing and that no application for renewal of fenbuconazole had been received, therefore its approval will expire on 30 April 2021.

Another Member State commented that it does not agree with the ADI set for 1,2,4-triazole and has proposed a higher value in the context of an ongoing renewal review. The Commission explained that this raises concerns about ensuring a harmonised approach between Member States when evaluating triazole substances. The Commission noted that Member States should use the reference

values established in the EFSA Conclusion as agreed by experts during the review of the TDM metabolites since these were the ones that have been subject to the widest scrutiny and agreed at expert level. Any reconsideration of values would need to be confirmed through peer review and agreed at Union level.

The Commission explained that it was reflecting on how to finalise the discussion on the topic and close the individual files in a consistent manner, also taking into account substances that are not under the remit of the TDMG and where confirmatory requirements had been established. The Commission mentioned that the pesticides residues section of this Committee was also discussing the assessment of TDMs to agree on an approach for assessing exposure in MRL procedures. Close cooperation between the two Committee sections is necessary to ensure a harmonised approach.

7. *Geraniol*

No news to discuss.

8. *Eugenol*

No news to discuss.

9. *Thymol*

No news to discuss.

A.05 Article 21 Reviews:

No news to discuss.

A.06 Amendment of the conditions of approval:

1. *New admissible dossiers to be noted:*

No news to discuss.

2. *Exchange of view on EFSA conclusions*

a) Azadirachtin

Point postponed.

3. *Draft Review/Renewal Reports for discussion:*

No news to discuss.

A.07 Basic substances:

1. *New dossiers received (for information)*

The Commission informed that dossiers for the following substances had been received:

- a) chitosan hydrochloride (extension to olive trees, amenity grassland, ornamentals, post harvest fruits, grapes as an elicitor to enhance resistance against pathogens)
- b) Dimethyl Sulfide (against truffle beetle in *Tuber melanosporum*, *Tuber* spp)
- c) Disodium citrate perhydrate (fungicide in apricot, apple, pear and potatoes)

- d) Sodium hydrogen carbonate (extension in citrus fruits as a post harvest application against *Penicillium*)
- 2. ***Exchange of views on EFSA Technical Reports***
 - a) Propolis extract

The Commission summarised the EFSA Technical Report. The Commission invited Member States to submit comments by 23 April 2019.
- 3. ***Draft Review Reports for discussion:***
 - a) *Castanea* and *Schinopsis* tannins
 - b) *Vitis vinefera* tannins

The Commission informed that the comments received so far from Member States are available on CIRCA BC. No discussion took place.

A.08 Guidance Documents:

1. ***EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)***

The Commission informed that comments received from Member States since the previous meeting are available on CIRCA BC. Based on a comment received, the Commission had made a clarification to the draft implementation plan.

Member States were informed about the content of the mandate sent to the EFSA on 11 March 2019 to review the Bee Guidance document. The mandate was uploaded on CIRCABC and is published on EFSA's website.

The Commission informed the Member States about the current status of the procedure to amend the uniform principles for bees.

One Member State indicated that its preliminary position is positive, indicated that June 2019 is still mentioned on the second page of the draft Commission Notice and asked for a timely notification of a workplan for the review of the Guidance Document. Another Member State repeated its opinion that the current draft is insufficient. This Member State was in favour of the mandate sent to EFSA and announced that it will submit a draft for an alternative path forward.
2. ***Draft Commission Notice – Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009 (SANTE/10407/2018 Rev.3)***

The Committee had no further comments on the draft Commission Notice. The Commission informed it will proceed with the publication.
3. ***Draft revised Guidance Document on generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013 (to take note)***

The Committee took note of the revised Guidance Document.
4. ***Updated list of endpoints to include a new field in the Identity Section (to take note)***

The Committee took note of an updated version of the List of EndPoints to include a new field in the Identity Section, enabling a reference to be added to a

document containing the details of the significant (confidential) impurities in order to facilitate the better determination of the reference specification and enable more efficient equivalence checks downstream. The field would also be included in the review/renewal reports for substances (Appendix 1).

Several Member States and EFSA had commented on the need to go further than this update to also revise the guidance on finalisation of reference specification post approval. The Commission invited Member States to indicate their interest in this activity with a view of setting up a discussion to move forward with an update.

5. ***Draft guidance document on Consideration of Soil Photodegradates in FOCUS-PELMO 5.5.3 –discussion on next steps***

The Commission suggested mandating EFSA to take over the last steps for finalising this guidance document which had been prepared by some Member States. The Commission invited the lead Member State for drafting this document to submit a short summary of the process so far, in order to mention this in the mandate to EFSA.

6. ***Working Document on emergency authorisations according to Article 53 (discussion)***

The Commission thanked Member States for the comments received and indicated that comments would be considered in a revised version of the document. The Commission invited Member States who had not commented yet to submit their views by 5 April 2019.

One Member State asked that further guidance on the threshold for scrutiny of emergency authorisations be included in the guidance. Another Member State asked for further clarity on certain aspects related to the use of PPPAMS. Another Member State mentioned the need for consistent approaches between Member States when granting emergency authorizations in relation to calculating the Harmonised Risk Indicator.

The Commission informed Member States that the final status of the document and the next steps in terms of consulting stakeholders was still to be determined.

7. ***Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02***

No news to discuss.

8. ***Defining Specific Protection Goals for environmental risk assessment***

The Commission summarised the actions so far and the comments received from three Member States. The Commission also presented the tentative process and timeline of the project to move forward. The Commission invited Member States to nominate by 23 April 2019 two experts per country to follow the whole process which will last for at least one year. The expertise of this experts should cover biodiversity, the regulatory framework (placing on the market of plant protection products, sustainable use), ecosystems, protection goals. A first Workshop is planned for 21 June 2019 with Member States experts. The Commission invited Member States to send further comments or questions which may be relevant for the workshop by 23 April 2019.

The Commission indicated that a similar workshop will be held with stakeholders in September (date to be defined) and that stakeholders will be updated about the process in the Plenary of the Stakeholder Advisory Forum of DG Health and Food Safety, which takes place in May.

9. ***Guidance Documents for biopesticides and low risk pesticides – update on progress***

The Commission informed that the Biopesticides Working Group agreed on the guidance document regarding SCLPs (e.g. Straight Chain Lepidopteran Pheromones). Once the internal discussion as regards the format and process for adoption will be clarified the Commission will post the guidance on CIRCA-BC for collecting the comments of Member States.

The Commission also informed about the development of the guidance documents on antimicrobials resistance and potential metabolites of concern.

10. ***EFSA's Administrative guidance on submission of dossiers and assessment reports and associated updates to relevant existing documents (to take note):***

- Combined Template to be used for Assessment Reports according to Regulation (EC) No 1107/2009 and Proposals for Harmonised Classification and Labelling according to Regulation (EC) No 1272/2008 Agreed by Member States' Competent Authorities in the SCoPAFF: Phytopharmaceutical legislation section. SANCO/12592/2012 –rev. 1.2, 6 October 2017 (Volume 1, Volume 2 and Volume 3).
- Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 (the Renewal Regulation). SANCO/2012/11251 rev. 4, 12 December 2014
- Guidance document on preparing lists of test and study reports according to article 60 of Regulation (EC) No 1107/2009. SANCO/12580/2012 - rev. 3.1, 17 May 2013
- Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013. SANCO/10181/2013– rev. 3, 12 December 2014
- including updated Document N3

The Committee took note of the draft administrative guidance and the updates to the four guidance documents listed above. For the EFSA administrative Guidance Document, the Committee agreed the following implementation schedule:

- For (supplementary) dossiers submitted to Member States and EFSA on or after 1 October 2019;
- For Assessment Reports (DAR/RAR) submitted to EFSA by Member States after 1 October 2020.

The updated procedural guidance documents apply as indicated in the version history of each document.

Concerning the checklists for Assessment Reports as included in the EFSA Guidance Document:

- The short-term Completeness Checklist for Assessment Reports (Appendix B1 of the Administrative guidance) is directly applicable and should be submitted together with DARs/RARs sent to EFSA after 1 April 2019. This 'short-term' list should be used until the 'long-term' or 'full' checklist will be implemented.
- The full Completeness Checklist for Assessment Reports (Appendix B2 of the Administrative guidance) should be used by RMS and submitted together with all DARs/RARs submitted to EFSA after 1 October 2020.

The United Kingdom submitted a declaration to be included in the summary minutes as follows:

The UK appreciates the reasons for requiring that studies evaluated in previous reviews are re-assessed in accordance with current standards. Nevertheless, this is contrary to the UK's understanding of the legislative focus on assessing only new studies and will entail significant additional work for both applicants and rapporteurs. In some cases, the extra work raises the safety standard; but for many substances it leads only to lengthy lists of data gaps which are not critical to the approval. This level of scrutiny and rigour is not sustainable and is delaying the renewal programme significantly.

Comments received from the European Crop Care Association (ECCA) related to the Guidance Document on preparing lists of test and study reports were made available to Member States ahead of the meeting but had not been taken into account for the current update. The Commission reminded Member States of the importance of such lists and making them available in a timely manner – see also point A.28.

A.09 Commission Regulation (EU) No 547/2011 and risk mitigation:

1. *Feedback about notification of additional phrases by MS (no news)*

No news to discuss.

2. *Risk Mitigation / list of risk reduction measures*

The Commission presented a first outline of an EU list of Risk Mitigation Measures (RMM). These measures had been compiled mainly from already existing (draft) guidance documents.

The document circulated in advance of the meeting was welcomed by Member States as a good starting point for consideration of risk mitigation at different steps of the review process of a substance (applicant's submission, Assessment Report, peer review and EFSA conclusions, Commission proposal) and/or of the (zonal/national) authorisation of the plant protection products.

The Commission clarified its intention to mention the risk reduction targets and minimal risk mitigation measures at the EU's approval/renewal stage, when the Risk Assessment conclusions are clearly calling for them. It should however not prevent Member States to adapt the measures to their local conditions or to the specific uses with alternative risk reduction measures or none in case of non exposure.

The first outline was illustrated with the example of cypermethrin and napropamid-M (see Points A.02 and A.03). The Commission invited Member States to submit their comments on the draft outline by 23 April 2019.

A.10 Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (to be noted):

No notifications received.

A.11 Notifications under Article 36(3) of Regulation (EC) No 1107/20091:1. *New notifications (to be noted)*

The Committee took note of 6 notifications received from 2 Member States, refusing mutual recognition of authorisation of plant protection products containing tri-allate, chlorotalonil and tebuconazole, milbemectin, propamocarb and cymoxanil (two notifications), and mild pepino mosaic virus.

As regard the last notification, it was notified for the Standing Committee meeting which took place in January but the note taking was postponed to allow for bilateral discussions among the authorising and the notifying Member States. During this Standing Committee meeting, the authorising Member State takes note but mentions it does not agree with the decision of the notifying Member State.

2. *Differences in application of article 36(3) amongst Member States*

Postponed.

A.12 New authorisations granted under Article 53 of Regulation (EC) No 1107/2009:1. *New notifications (to be noted)*

The Committee took note of 33 emergency authorisations received from 12 Member States between the 22 January 2019 and the 15 of March 2019 via the PPPAMS, which are summarised as follows:

MS	Active substances	Functions
AT	Captan	fungicide
AT	Cypermethrin	insecticide
AT	8-Methyl-2-decanol propanoate	semio-chemicals
AT	Ethoprophos	insecticide
AT	Tefluthrin	insecticide
BE	Fluopyram Prothioconazole	fungicide
BE	1-Naphthylacetic acid (1-NAA)	plant growth regulator
BE	Cyantraniliprole	insecticide
BE	Thiamethoxam	insecticide
BG	Quinclorac	herbicide
BG	Oxadiazon	herbicide
EE	Fludioxonil Metalaxyl-M Thiamethoxam	fungicide insecticide
ES	Cymoxanil Famoxadone	fungicide
ES	<i>Aureobasidium pullulans</i> (strains DSM 14940 and DSM 14941)	bactericide
FI	Quinclamine	herbicide
FR	Lime sulphur (calcium polysulphid)	fungicide
FR	Sodium hypochlorite	bactericide

FR	Pendimethalin	herbicide
FR	Aclonifen	herbicide
FR	Metalaxyl-M	fungicide
LT	Fludioxonil Metalaxyl-M Thiamethoxam	insecticide
LT	Imidacloprid Pencycuron	insecticide
LU	<i>Metarhizium brunneum</i> strain Cb15-III	insecticide
LU	Plant oils/ Rape seed oil Pyrethrins	insecticide
LV	Sodium silver thiosulphate	plant growth regulator
LV	2-Methyl-3-buten-2-ol 2-Methyl-6-methylene-2 7-octadien-4-ol (ipsdienol) 4 6 6-Trimethyl-bicyclo[3.1.1]hept-3-en-ol (S)-cis-verbenol)	attractant
LV	2 6 6-Trimethylbicyclo[3.1.1]hept-2-ene (alpha-Pinen) 2-Methyl-6-methylene-2 7-octadien-4-ol (ipsdienol) 4 6 6-Trimethyl-bicyclo[3.1.1]hept-3-en-ol (S)-cis-verbenol)	attractant
LV	Imidacloprid Pencycuron	fungicide insecticide
LV	Fludioxonil Metalaxyl-M Thiamethoxam	fungicide insecticide
NL	Paraffin oil/(CAS 8042-47-5)	insecticide
NL	Cyantraniliprole	insecticide
NL	Plant oils/ Rape seed oil Pyrethrins	insecticide
SI	Acetamiprid	insecticide

The Commission also mentioned its intention to analyse in the future the notifications received, focusing on different aspects. For instance as regards neonicotinoids, from June 2016 until the day of the current meeting a total of 108 notifications on several crops were received via the PPPAMS from 16 Member States. For sugar beets, so far 18 Emergency Authorisations were authorised in 2018. A detailed summary is made available via CIRCA BC.

2. *Antimicrobials notified 2017/2018 (update)*

The Commission informed about the update of the document “*Antibiotics used in Crop Protection*” (SANTE/973/2000 rev 17), which included additional notifications from the Member States for the year 2018. The Commission also informed about a position paper under preparation to encourage a careful use of antibiotics in plant protection schemes (IPPC – Commission on Phytosanitary Measures in Rome, on 1-5 April 2019).

3. *Draft Commission Implementing Decisions under Art 53(3)*

The Commission presented two draft Implementing Decisions and invited Member States to send comments by 23 April 2019.

The two Member States to whom the draft Decisions are addressed explained the reasons for their granting of the authorisations in question and did not agree with the draft Decisions. One Member State also underlined that EFSA did not consider their practical concerns. That Member State indicated that it is currently looking for alternatives, and also indicated that a zonal application for a possible alternative had been submitted for which the evaluation is ongoing.

Other Member States also raised concerns as regards the methodology used by EFSA to analyse the justification of the authorisations or disputed that EFSA has the competence to do such an analysis. One Member State criticised that this specific analysis was done for some active substances, but not for others, and therefore is politically motivated. Another Member State indicated that other substances should be looked at. A further Member State stressed that there are more and more emergency authorisations over the years because of the progressive banning of active substances leading to a reduction of availability of plant protection tools.

A.13 Plant Protection Products Application Management System (PPPAMS):

1. *Updated EPPO codes*

The discussion was postponed.

A.14 News from European Food Safety Authority (EFSA):

The delegate of EFSA presented the administrative guidance on submission of dossiers and assessment reports (see point A.08.10), and explained that the comments received from Member States after the presentation to this Committee in December were considered in the revised document.

Further, EFSA reported that the implementation of the new scientific criteria to identify endocrine disrupting properties is progressing, i.e. active substances currently under peer review are discussed in light of these new criteria. The next meeting of the Pesticides Steering Network was announced and will take place on 9 and 10 April. EFSA also acknowledged receipt of the mandate for statement on conducting the environmental exposure and risk assessment for transition metals.

A.15 Improving the efficiency of the process of a.s. approval – update on on-going activities including feedback of MS:

Covered under points A. 08.10 and A.09. No additional discussion took place.

A.16 News from Health and Food Audits and Analysis (SANTE, Directorate F, former FVO):

No news to discuss.

A.17 News from Sustainable Use Directive (Directive 2009/128/EC):

No news to discuss.

A.18 Minor Uses:

The EU Minor Uses Coordination (MUCF) is now fully depending on voluntary assessed contributions from Member States. Although the MUCF has received positive responses from 14 Member States, funds for 2019 are not yet secured. In the

Annual General Meeting of all funding countries, it was suggested to discuss the issue of the long-term funding of the Coordination Facility at the AGRIFISH Council.

The Commission reminded the Member States that they had all acknowledged the benefits of the work of the MUCF and strongly encouraged all Member States to provide the financial contribution to the MUCF as agreed in the Council.

Furthermore, the Committee was informed that:

The third Stakeholder Advisory Forum of the MUCF took place on 26 February 2019 and was well attended with around 40 stakeholders from a wide range of countries and organisations. The full report of the Stakeholder Advisory Forum will soon be made available on the Minor Uses Website (www.minoruses.eu).

The Guidance Document on Minor Uses will provide more clarity regarding the rules for authorisation of minor uses and contribute to further harmonisation between Member States. The document will be forwarded to the Standing Committee for final discussion and adoption.

The meetings of the Commodity Expert Groups and Horizontal Expert Group will be held in Brussels from 26 to 28 March 2019. More than 100 participants from 20 different countries have registered.

A.19 Progress Report on Low Risk Active Substances (update):

The Commission thanked the Member States which had provided information updating about their most recent actions regarding low-risk products and IPM implementation. The progress report has been updated accordingly and will be sent to the AGRIFISH Council in the coming weeks. The Presidency will then decide on how it will be brought to the attention of the Council.

A.20 Court cases:

The Commission shared information on the following court cases:

C-616/17 (Blaise) – Advocate-General opinion published on 12 March 2019;

T-716/14 - (Tweedale) and T-329/17 (Hautala and others)– vs EFSA: Judgment of the General Court published on 7 March 2019;

T-178/18: Bruxelles Capital Region vs Commission: Order of 28 February 2019 dismissing the application as inadmissible.

A.21 Endocrine Disruptors.

The Commission informed that the first Better Training for Safer Food (BTSF) course on the application of the ED guidance document had taken place in Brussels on 6-7 February 2019. The presentations and the video recording of the first training are uploaded on CIRCABC in the folder "Guidance documents and finalised projects". The feedback received from the participants of the first training is overall very positive. Their comments will be taken into account, as far as possible, to further improve the 2nd training, which is confirmed for 19-20 September 2019. The format will be the same as for the first: up to two experts per Member States (one for the plant protection products sector and one for the biocides sector) will be supported financially. The experts from each Member State should possibly cover both expertise in toxicology and ecotoxicology, and where possible, different from those attending the first training.

A.22 Interpretation issues:

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

a) Follow-up in situ generation (update)

The Commission informed about a first draft discussion paper regarding the possible status of in-situ generated substances under the current regulatory framework. The Commission invited Member States to submit their comments on the draft paper by 23 April 2019.

b) New case Herbie – soil fumigation

The Commission presented the case and an explanation why this product would not be considered a PPP. The Commission invited Member States to submit their comments on the case by 23 April 2019.

c) New case: biofumigation.

The Commission presented the case and an explanation why this product would be considered a PPP. The Commission invited Member States to submit their comments on the case by 23 April 2019.

A.23 Classifications under Regulation (EC) No 1272/2008:

1. *Status of harmonised classifications (summary table for info)*

Postponed.

2. *General update*

a) Draft amendment to Regulation (EC) No 844/2012 regarding the submission of dossiers, by the Rapporteur Member State, for harmonised classification and labelling to ECHA

The Commission informed about the comments received by two Member States. A slightly amended version taking up several changes is available on CIRCABC. Comments remain welcome. The same draft was presented to the Meeting of the Competent Authorities for REACH and CLP (CARACAL) on 20 March.

b) The Commission debriefed on a discussion held by the Post-Approval Issues Group (PAIG) on 15 March, regarding approaches and practices in Member States to classification changes and their impact on the authorisations, notably the label. Classification and the update of it remains the obligation of the suppliers. Accordingly, suppliers are obliged to notify each Member State where a product is authorised in case they consider that a change in classification is warranted. They have to apply, where relevant, for an amendment of the authorisation, which includes the approved label. For more severe classifications, the notification obligation may also flow from Article 56. In accordance with the CLP Regulation, suppliers have to follow applicable harmonised classification for substances when classifying the product. The discussion documents from the PAIG will be uploaded on CIRCA BC.

A.24 Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005):

No news to discuss.

A.25 Report from working groups:

The discussion was postponed.

A.26 OECD and EPPO:

a) General update

b) Recommendation of the Council on Countering the Illegal Trade of Pesticides

The discussion was postponed.

A.27 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations:

The Commission informed about the detected presence of matrine, an alkaloid originating from a plant extract of *Sophora spp.* which is not approved as active substance in plant protection products but has been found in fertilisers and the so-called 'auxiliary materials'. The Commission invited Member States to connect with their enforcement authorities for both, Plant Protection Products and Fertilisers. DG SANTE will inform the Fertilisers colleagues of DG GROW.

Furthermore, the Commission gave an update on substances for which MRLs were lowered or residue definitions changed, or which were moved to Annex IV of Regulation (EC) No 396/2005 (no MRL needed), in the meeting of the Pesticides Residues section of the Committee on 21-22 February 2019. This may have an impact on authorisations granted by Member States.

Following a request in the last meeting of the Post Approval Issues Group (PAI) group, the Commission clarified the approach for the implementation of the PRIMo tool rev. 3 for exposure assessments, as agreed with Member States in the meetings of the Residues section of the Committee in November 2017 and confirmed in February 2018.

A.28 Lists of tests and studies relied upon for active substance assessments:

This point was covered under A 08.10. The Commission reminded Member States of the need to make available the final lists of tests and studies used and relied on during assessment of active substances as soon as possible after the finalisation of the peer-review process. Generic companies had expressed concerns about the lack of time to negotiate access to studies and to finalise their data packages required for the Article 43 process.

A.29 Propiconazole – revised Renewal Report including the agreed toxicological reference values (for taking note):

The Committee took note of the revised Renewal Report.

France provided the following declaration:

France can support the amendment of the renewal report of propiconazole in order to add several toxicological reference values, including an ArfD lower than the previous EU agreed value.

However, France opposes to the establishment of import tolerances for active substances, such as propiconazole, where the approval has been withdrawn or has not been renewed in the EU due to public health concerns.

A.30 Scientific publications and information submitted by stakeholders:

The Commission informed the Committee about a number of documents submitted by stakeholders and uploaded on CIRCABC, which cover a series of aspects, including a new position paper as regards the proposal for an amendment to the Drinking Water Quality Directive currently under Co-Decision by the Council and the Parliament.

A.31 Date of next meeting(s).

The next meetings are: Appeal Committee (for vote on the non-renewal of approval of chlorpropham) 11 April, 15 April (possible opinions for current points B.09 and C.05), and 20-21 May (next regular meeting).

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of the low risk active substance ABE-IT 56 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/11228/2018 Rev. 2).

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance chlorothalonil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/10186/2018 Rev. 1).

The Commission presented the draft Regulation and the draft review report, and reported on comments received from the applicant, stakeholders and third countries.

The letters from stakeholders underlined the importance of chlorothalonil as a multi-site fungicide for several crops and in particular for *Septoria tritici* in wheat and *Ramularia* in barley. However, given the risks and data gaps identified, the Commission considers that the nature of these risks overrule economic considerations.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of the active substance 1-methylcyclopropene, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11631/2018 Rev. 2)

The Commission presented the revised draft Regulation and the draft review report, highlighting the changes introduced since the last meeting of the Committee in January 2019, in particular the specific provisions for the removal of 1-methylcyclopropene from Regulation (EU) 2015/408 on candidates for substitution.

Four Member States indicated that they could not support the draft for 1-methylcyclopropene to be categorised as low-risk substance due to the conditions of use and the risk mitigation measures to be set up following the risk assessment of the products at national level. These Member States indicated that in general they would support a renewal but not as low-risk substance. Other Member States indicated that they would also support a draft along this line. The Commission informed that it will consider amending the draft Regulation and draft Review Report accordingly as soon as possible.

Vote postponed.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance isoxaflutole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11653/2017 Rev. 2)

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance carvone in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11718/ 2018 Rev. 0)

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the low-risk active substance *Bacillus subtilis* strain IAB/BS03, 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/10318/2019 Rev. 1).

The vote was postponed because the inter-service consultation was not yet finalised by the time of the meeting. The Commission invited Member States to send any further comments by 5 April 2019.

Vote postponed.

- B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of the active substance dimethenamid-P, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11149/2018 Rev. 1)**

The vote was postponed because the inter-service consultation was not yet finalised by the time of the meeting. The Commission asked Member States to indicate their provisional positions on the draft during the meeting.

Vote postponed.

- B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulations (EU) No 22/2013 and (EU) No 540/2011 as regards the conditions of approval of the active substance cyflumetofen (Draft Review Report SANCO/12618/2012 Rev. 2)**

Vote taken: Favourable opinion.

- B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation as regards the as regards the extension of the approval periods of the active substances alpha-cypermethrin, beflubutamid, benalaxyl, bentiavalicarb, bifenazate, boscalid, bromoxynil, captan, carvone, chlorpropham, cyazofamid, desmedipham, dimethoate, dimethomorph, diuron, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, isoxaflutole, metalaxyl-m, methiocarb, metribuzin, milbemectin, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, s-metolachlor and tebuconazole, amending the Annex to Implementing Regulation (EU) No 540/2011**

The vote was postponed because the inter-service consultation was not yet finalised by the time of the meeting.

Vote postponed.

- C.01 Exchange of views of the Committee on a draft Commission Regulation amending Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards bees principles for evaluation and authorisation of plant protection products.**

Discussed together with point A.08.1.

- C.02 Exchange of views of the Committee on a draft Commission Regulation (EU) modifying Annex III of Regulation (EC) 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (SANTE/10257/2018)**

The Commission presented the draft Regulation, which had been revised following the comments received from the Member States.

One of the main comments raised by the Member States was the possibility to identify unacceptable co-formulants based on risk in addition to the consideration of hazards.

The Commission indicated that this is already foreseen by recital 3, but further clarification had been added in that recital following the comments received. Procedures for future identification of unacceptable co-formulants based on risk could be detailed in the Implementing Regulation setting rules to identify unacceptable co-formulants, which is planned for discussion after conclusion of the RPS procedure for this Regulation populating for the first time Annex III.

The Commission asked in particular whether the Member States could support the proposed limit of 0.1% for unacceptable impurities in co-formulants and underlined that the sole purpose was to facilitate enforcement, i.e. distinguishing between intentional addition and unintentional presence of the substances. One Member State indicated that for some of the substances detecting 0.1% might not be feasible in all laboratories for all substances. Other Member States advocated a lower limit of 0.01 % which in their view would increase the level of protection while not creating analytical problems.

The Commission asked Member States whether they support the proposed transitional period of 1 year for implementing the draft Regulation. Three Member States indicated that a preliminary analysis of their national authorisations had shown that very few formulations might ultimately need to be amended, since most of the co-formulants listed are already out of the market. Therefore 1 year should be sufficient. Four other Member States highlighted that they would be in favour of longer transitional periods because the number of authorisations to be screened in some Member States are up to a few thousands, even if maybe only few would ultimately need to be amended.

Two Member State suggested establishing an obligation for the authorisations holders to check whether their plant protection products on the market contain any of the listed unacceptable co-formulants and then apply for amendment of the authorisations concerned. The Commission indicated it will reflect on the possibility to insert such a provision, but in any case it would be the ultimate responsibility of the Competent Authorities to check and ensure that no unacceptable co-formulants are on the market. The reason is that only the Competent Authorities hold all the information on the composition of the formulations, as due to data protection/confidentiality issues, which is a right of the co-formulants suppliers, not all authorisation holders know the exact composition of the PPP.

Five Member States requested to delete the 2nd part of recital 1: in their view there are cases where it is acceptable that a substance can be a co-formulant or an active substance (or synergist or safener), for instance depending on the concentration used. The Commission indicated that it will reflect on this point.

The Commission invited Member States to submit written comments on the draft Regulation by 5 April 2019.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance indoxacarb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/10730/2018).

The Commission informed the Member States about its intention to mandate the EFSA to organise an expert meeting on ecotoxicology to discuss the assessment of the

risk for mammals and bees, which had not taken place during the peer review process. Due to the relevance of these aspects for the decision making for this active substance, an expert meeting discussion seems necessary.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance methiocarb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11710/2018)

The Commission informed that comments had been received from five Member States and from the applicant since the last meeting. Member States supported the non-renewal drafts of the Commission. The Commission had revised the draft renewal report with the new expiry date recently extended for administrative reasons, and asked the Member States to send any further comments by 23 April 2019.

C.05 Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 686/2012 as regards the nomination of rapporteur Member States and co-rapporteur Member States for the active substances glyphosate, lambda-cyhalothrin, imazamox and pendimethalin and amending Implementing Regulation (EU) No 844/2012 as regards the possibility that a group of Member States assumes jointly the role of the rapporteur Member State

The Commission presented the draft Regulation, noting that it had been made available to the Committee only a few days ago so that the vote could not take place at this meeting. No Member State had any further comments on the draft Regulation. The Commission indicated that the vote would be held at the meeting of another section of the Standing Committee on 15 April 2019.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance thiophanate-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 Renewal Report SANTE/11254/2018).

The Commission informed about the recent RAC Opinion on thiophanate-methyl which confirmed the current harmonised classification of this substance as mutagen category 2 (and not mutagen category 1B, as initially proposed by the Rapporteur Member State). The Commission reminded that the Rapporteur Member State had already revised their proposal in November 2018. However, the Rapporteur Member State had indicated at that time that the revision would not change their proposal for non-renewal of the substance. The Commission asked the rapporteur Member State and EFSA to assess whether the RAC conclusion now available might or not significantly influence the conclusion on thiophanate-methyl. The Commission indicated that from a preliminary assessment the overall concerns about thiophanate-methyl are such that a proposal for non-renewal remains appropriate.

The Commission also informed that the standard grace periods of 12 months from the date of entry into force of the Regulation are maintained for thiophanate-methyl. The Commission suggests that this period is adopted for most active substances, except for

very few exceptions (e.g. the past case of iprodione proposed for classification as toxic for reproduction, Category 1B and with levels of various metabolites in groundwater exceeding the acceptable limits), where clear acute risks for the consumers are identified.

One Member State indicated that it agreed with such standard grace periods and pointed out that, with such non-renewal decision, no insecticides are left for minor uses and risk managers should take into account those facts when taking decisions.

The vote was postponed as the TBT notification process was still ongoing.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance dimethoate, 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/11494/2018).

The Commission informed that the standard grace periods of 12 months from the date of entry into force of the Regulation are maintained for dimethoate. One Member State indicated that they support such provision and reminded that no alternatives to dimethoate are available for their farmers.

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the renewal of the active substance tolclofos-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 Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11272/2018)

No news – TBT notification process ongoing.

C.09 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance desmedipham, 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/10556/2018).

No news – TBT notification process ongoing.

M.01 The Commission informed that:

- the Appeal Committee for chlorpropham will take place on 11 April at 9:30;
- a vacancy for a national expert is published and the vacancy notice has been also shared on CIRCA BC;
- cyazofamid will be also discussed under point A.03.03;
- an update of the amendments to the General Food Law will be given at the next meeting of this Standing Committee.

One Member State asked to discuss the conditions of approval for maleic hydrazide. The implementation of the conditions set are causing unproportioned costs to industry, in particular to potato industry. Current scientific data indicate that the

metabolite, which was the reason for setting the current conditions of approval, is of no concern if a risk assessment is conducted which indicates that the conditions of approval are unproportionately high. The Commission indicated that it would reflect and the issue would be discussed at the next Standing Committee meeting(s).

Another Member State inquired if fees could be charged by Member States which take over dossiers from the UK after Brexit. The Commission indicated that Member States are entitled to charge fees.