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Standing Committee on Plants, Animals, Food and Feed
Section *Pesticides Legislation*
24-25 MAY 2018

CIRCABC Link: ***https://circabc.europa.eu/w/browse/99e8a049-5c0d-47e9-a710-ffc730c6c9b6***

SUMMARY REPORT

A.01 Summary Report of previous meetings.

The Committee was informed that the reports from January and March were being finalised and would be published in due course.

A.02 New active substances:

1. New admissible dossiers to be noted:

   No new admissible dossiers to be noted.

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

   a) *Beauveria bassiana* PRI 5339

   The active substance is an entomopathogenic fungus, isolated from the wild.

   No critical areas of concern were identified in the EFSA conclusion, but only some data gaps. The applicant was given the opportunity to submit comments on the conclusion and the Commission intends to present a first draft Review Report in July.

   b) *Bacillus subtilis* IAB/BS03

   The active substance is a bacterium with fungicidal properties. The EFSA conclusion was pre-notified in April and the applicant was invited to submit comments. The Commission intends to present a first draft Review Report in July.

   c) Asulam-sodium

   Member states were invited to provide their comments by 8 June 2018. Draft review reports and Regulations would be made available in July.

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

   a) Flutianil

      Given the outcome of the assessment of the European Chemicals Agency of the proposal for classification, the Commission has asked EFSA to provide a statement about which concerns identified in the conclusions are still valid.

      EFSA confirmed that such statement is under finalisation and will be submitted soon.

   b) Metschnikowia fructicola NRRL Y-27328

      The Commission presented the draft review report for the approval of M.fructicola and referred to the comments received from the applicant and from one Member State. Other Member States were invited to provide their comments by 8 June 2018.

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play

   The Commission informed that the Commission Decision concerning the fifth renewal programme presented to the Standing Committee in March 2018 should have been adopted through a different procedure and no opinion from the Standing Committee was necessary. The document will be published in the Official Journal shortly.

2. Exchange of view on EFSA conclusions:

   a) Trinexapac

      The Commission outlined the conclusion on trinexapac, which has been pre-notified in March 2018. The applicant was invited to comment. The Commission intends to present a draft review report and Regulation in July.

   b) Rimsulfuron

      The Commission explained that the EFSA Conclusion of rimsulfuron had been made available to the applicant, Member States and the Commission and that the applicant had been consulted. Member States were invited to comment on the EFSA conclusion. A draft renewal report and Regulation would be made available in one of the next meetings of the Committee.

   c) Ethoprophos

      The Commission explained that the EFSA Conclusion on ethoprophos had been made available to the applicant, Member States and the Commission and that the applicant had been consulted. A draft renewal report and Regulation would be made available in July.

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

   a) Chlorpropham

      The Commission informed the Committee about the state of play for the proposal on non-renewal; the interservice consultation had been finalised at the end of March but the TBT commenting period of 60 days was still ongoing and does not allow to proceed with a vote in this session. Positions from

Member States and the RMS have been discussed as well as new comments from the applicant on the revision 1 of the draft non-renewal report. Several stakeholders' expressions of importance of substance in the horticultural sector had also been made available in CIRCABC. The Committee was informed that the Commission intended to submit the proposal for a vote in July. Member States were invited to send their views by 8 June 2018.

b) Quinoxyfen (short update only)

The Commission informed the Committee that the internal procedure is nearly finalised which will be followed by the TBT notification which lasts 60 days.

c) Mecoprop-P

The Commission informed the Committee about the new state of play of the renewal of approval of mecoprop-p. After careful analysis of the dossier, it appears that the critical area of concern identified by EFSA comes from a non-acceptable study on dermal absorption. As guidance in place in this area remained stable, there is no legal ground for a renewal of mecoprop-p with a request for confirmatory information. The only possibility is not to renew the approval of mecoprop-p. The Commission also informed that the revised renewal report was shared with the applicant. It invited Member States to provide comments by 8 June 2018.

d) Copper compounds

The Commission presented the content of the draft renewal report for copper compounds, the first preliminary comments received by the applicant and a position paper form IFOAM. The report is the background document for a proposal of renewal of copper as candidate for substitution with restriction of the maximum application per hectare and per year to 4 Kg/ha. Moreover, taking into account the need for elaboration of specific guidance for environmental risk assessment of metals as active substances in plant protection products, the period of approval will be limited to five years to allow anticipation of the re-assessment to when the guidance will be available taking into account developments available under other EU regulatory areas. The RMS informed of the finalisation of the assessment of the final report on monitoring data which had been submitted by the Task Force end of December 2017. One Member state commented on the lack of flexibility of the maximum application rate and one Member State express concern for the risk to aquatic organisms and workers. Member States were invited to provide their comments by 8 June 2018.

e) Mepanipyrim (short update only)

The Commission informed the Committee that the internal procedure is ongoing which will be followed by the TBT notification which lasts 60 days. The Commission promised to consider the proposal of a Member State as regards the option for confirmatory data.

f) Tribenuron

The Commission informed the Committee that some inconsistencies had been found in the EFSA conclusion. These will be corrected and a new version of the conclusion will soon be published. The result of the discussions with EFSA is that the only critical area of concern will be deleted which concerned

the potential for groundwater exposure above the parametric drinking water limit of 0.1 µg/L by two relevant metabolites. Member States were invited to send their comments by 8 June 2018.

g) Flurtamone (short update only)

The Commission informed the Committee that the TBT notification had been launched and once completed a vote is foreseen for the July meeting of the Committee.

h) Propiconazole (short update only)

The Commission informed the Committee that the interservice procedure was underway and once completed would be followed by the TBT notification lasting 60 days.

i) Etoxazole (short update only)

The Commission informed the Committee that the internal procedure is nearly finalised which will be followed by the TBT notification which lasts 60 days.

j) Pethoxamid (short update only)

No item raised.

k) Methoxyfenozide

- The Commission presented the content of the draft renewal report for methoxyfenozide, which supports the potential renewal of the substance as a candidate for substitution restricting use to greenhouses for fruiting vegetables. In addition, the draft requests confirmatory data to complete the assessment concerning a comparative *in vitro* metabolism study, mechanistic data to rule out endocrine disrupting (ED) mediated mode of action, effect of water treatment on the nature of residues in drinking water.

- The applicant commented on this first draft and the Commission will consider the comments which, among others, require more time to present studies on ED mode of action considering the ongoing work on the guidance. On this point, the Commission will take into account the deadline recently proposed in other comparable decisions for consistency. Three Member States expressed their concern about the restrictions proposed. Member States were invited to provide their comments by 8 June 2018.

l) Desmedipham

The Commission informed the Committee about the main concerns in the EFSA conclusion and presented the draft review report for non-renewal. Member States were invited to send their views on that proposal by 8 June 2018.

m) Phenmedipham

The Commission informed the Committee about the main concerns in the EFSA conclusion and presented the draft review report for non-renewal. Member States were invited to send their views on that proposal by 8 June 2018.

n) Chlorothalonil

The Commission informed the Committee about the main concerns in the EFSA conclusion. The Commission will make a first draft available to the Member States before 6 June 2018 via CIRCABC. Member States were invited to send their views on that draft by 6 July 2018.

o) Indoxacarb

The Commission informed the Committee about the main concerns in the EFSA conclusion. The Commission will make a first draft available to the Member States before 15 June 2018 via CIRCABC. Member States were invited to send their views on that draft by 15 July 2018.

A.04 Confirmatory Data:

1. Dithianon (tour de table of voting intentions)

   The TBT notification has been launched but is not finalised.

   Member States were asked to express their position on the current draft to restrict the use to non-edible crops based on the assessment of the confirmatory data. No qualified majority would be reached in favour of the draft presented by the Commission.

   The RMS confirmed that they will assess the new data prepared by the applicant to check whether or not this new data would indeed resolve the outstanding issues.

2. Terbuthylazine (short update only)

   The Committee was informed that following the previous discussion on how to proceed with the issue for groundwater and the lack of reference values for the LM groundwater metabolites, a mandate would be sent to the EFSA Scientific Panel on Plant Protection Products and their Residues (PPR Panel) to look at the specific issue of setting reference values only. This is considered appropriate since there remains a question about whether the only viable option to address the issue is to conduct new vertebrate studies. Since the use of animal studies should be a last resort it is considered appropriate to consider this specific issue before moving forward with decision making.

3. Iprovalicarb (review report to be noted)

   Note taking postponed.

4. Ipconazole (review report)

   Postponed.

5. Urea (review report)

   Postponed.

6. Cyflumetofen (short update only)

   The Committee was informed that the Commission started the internal consultation and that the draft to restrict the condition of approval of cyflumetofen may be planned for vote in July.

7. Malathion (restriction of approval)

   The Commission informed the Committee that the draft Implementing Regulation restricting the approval of malathion, which was withdrawn from vote in March will be tabled for a vote at the next meeting.

A.05 Article 21 Reviews.

No points for discussion.

A.06 Amendment of the conditions of approval:

1. New admissible dossiers to be noted:

   No new admissible dossiers to be noted.

2. Exchange of view on EFSA conclusions:

   No points for discussion.

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

   No points for discussion.

4. SCLP new compounds belonging to the approved group:

   The Commission presented the amended draft review report rev.14 on SCLP to include two new compounds (8Z)-tetradec-8-en-1-yl acetate and (Z)8-tetradecen-1-ol for which recently an assessment has been finalised in line with Guidance document SANCO/5272/2009 rev3. Member States were invited to send their comments by 8 June 2018 as it is intended to submit the draft for taking note at the next meeting in July.

A.07 Basic substances:

1. Pilot projects: state of play

   No new developments since last meeting.

2. New dossiers received (only for information)

   a) clayed charcoal (extension)

      The Commission informed the Committee that a dossier for the extension of the approval of clayed charcoal has been submitted.

3. Exchange of views on EFSA Technical Reports

   No new developments since last meeting.

4. Draft Review Reports for discussion:

   a) Landes pine tar (short update only)

      The Commission informed the Committee about the main concerns expressed in the EFSA technical report. Member States were invited to send their views on that draft by 29 June 2018.

   b) Lecithin extension (to be noted)

      The Standing Committee took note of the revised review report on lecithins (Doc. SANCO/12798/2014 rev.3) to approve the extension of uses on strawberries, raspberries and potato.

c) Onion oil

The Commission presented the draft review report for onion oil. Given the overall unproblematic profile of this substance, the Commission intends to move ahead as quickly as possible and will try to table a draft for a vote at the meeting in July.

Member States were invited to send their views by 8 June 2018 at the latest.

A.08 Exchange of views on Guidance Documents:

1. Draft revised Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (short update)

   The Commission informed the Standing Committee on the state of play of the draft revised Guidance document. A final revised version will be distributed in view of the meeting in July.

2. Draft revised Guidance Document on Zonal Evaluation, Mutual Recognition Withdrawal and Amendment of Authorisations under Regulation (EC) No 1107/2009 (short update)

   The Commission informed the Standing Committee on the state of play of the draft revised Guidance Document. A final revised version will be distributed in view of the meeting in July.

3. Draft Mandate for a Technical Guideline on the Structure of the Biological Assessment Dossier (to be noted)

   The Standing Committee took note of the Mandate to a group of Member State experts led by France to develop a guidance document on the structure of the biological assessment dossier.

4. Draft revised template to notify intended zonal applications under Article 33 of Regulation (EC) No 1107/2009 (SANCO/12544/2014 rev. 1, to be noted)

   The template to notify zonal applications was revised to clarify the various pieces of information applicants should submit to the Member States where they seek an authorisation, especially for applications for low-risk products.

   The Standing Committee took note of the revised template.

   The template will apply immediately and will be uploaded on the European Commission’s website.

5. EFSA Guidance of Dermal Absorption (SANTE/10591/2018, to be noted)

   The Commission explained that the Guidance Document (adopted by EFSA in May 2017) had not been yet noted by the Committee because the intention was initially to note it together with the updated Communication on data requirements. Following the request from some Member States and considering that discussions on the Communication on data requirements are still ongoing, the Commission invited the Committee to note the Guidance Document at this meeting.

   A clarification was added to the implementing page in order to clarify the threshold value agreed to discriminate plant protection products that are "concentrates" from those that are "dilutions".

   The Guidance Document was noted.

It will apply from 25 August 2018.

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

   The Commission informed the Member States that a revised Commission Notice for a stepwise implementation of the Bee Guidance Document will be tabled at the next Standing Committee meeting in July.

7. 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 (short update).

   The Commission presented the draft revised guidance document developed by France and Germany. The version takes into account comments made by Member States' risk assessors. Member States were invited to send their comments by 29 June 2018 as it is inended to submit the draft for taking note at the next meeting in July.

8. Draft revised Guidance Document on data protection according to Regulation (EC) No 1107/2009 (short update)

   Discussed under agenda point B.14

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

Three notifications were submitted by Luxembourg concerning the active substance thiacloprid.

The Committee took note of the notifications provided by Luxembourg.

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

1. New notifications (to be noted)

   Three notifications have been sent from Germany (Star Captan 80, Prolectus, Consento). One notification concerns an authorisation from outside the central zone. One notification identifies shortcomings in the risk assessment performed by the reference Member State, but does not refer to any special circumstances in the territory of the recognising Member State. Both notifications therefore do not fall under the provisions of Article 36(3).

   The Committee took note of one notification submitted by Germany concerning the product Prolectus.

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

   Postponed.

3. On-board fumigation of grain

   No further comments were received after the last meeting. The Commission suggested to close the point after the July meeting as there seems to be no need for further discussion about harmonisation.

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

EFSA Technical Report_Art. 53(2) examination of emergency authorisations for neonicotinoid active substances:

EFSA presented the main conclusions of the 7 reports on the evaluation of emergency authorisations for neonicotinoid active substances. The Commission will further analyse the conclusions in these reports and further discuss the results in the meeting of the Standing Committee in July 2018.

One Member State informed developing a national assessment scheme to assess Art. 53 applications as an alternative to the EFSA Art. 4(7) assessment protocols.

Thiacloprid (Austria)

(E,E)-8,10-Dodecadien-1-ol, (Z)-11-Tetradecen-1-yl acetate, (Z)-9-Tetradecen-1-yl acetate, Dodecan-1-ol, Tetradecan-1-ol (Belgium)

Aclonifen (Belgium)

Cyantraniliprole (Belgium)

Ethylene (Belgium)

Quinclorac (Bulgaria)

Fenoxycarb (Germany)

Captan (Germany)

Cydia pomonella Granulovirus (CpGV) (Germany)

2,5-Dichlorobenzoic acid methylester (Germany)

Abamectin (aka avermectin) (Estonia)

Chlorantraniliprole (Finland)

Clomazone (Finland)

Quizalofop-P-ethyl (Finland)

Pendimethalin (France)

Aclonifen (France)

Chlorantraniliprole (France)

lambda-Cyhalothrin (France)

Spinosad (France)

Acibenzolar-S-methyl (benzothiadiazole) (France)

Metobromuron (France)

Oxadiazon (France)

Dimethyl disulphide (France)

Fosetyl (France)

Cyprodinil, Fludioxonil (France)

Spinosad (France)

Metribuzin (France)
Sulphur (France)
Trifloxystrobin (France)
Mesotrione (France)
Metribuzin (France)
Bentazone (France)
Cyantraniliprole (France)
Phosmet (France)
Flonicamid (IKI-220) (France) FR
2,4-D (France)
Gibberellic acid (France)
Tefluthrin (France)
Metalaxyl-M (Greece)
Propanil (Greece)
Pyrithiobac sodium (Greece)
Trifloxysulfuron (Greece)
Pretilachlor (Greece)
Molinate (Greece)
Oxadiazon (Greece)
Quinclorac (Greece)
Lavandulyl senecioate (Greece)
Bentazone (Greece)
Ioxynil (Greece)
Iprodione (Greece)
Etofenprox (Greece)
MCPA (Greece)
Abamectin (aka avermectin) (Ireland)
Spirotetramat (Italy)
Pyraflufen-ethyl (Italy)
Phosmet (Italy)
Plant oils/ Rape seed oil, Pyrethrins (Lithuania)
Beauveria brongniartii (Lithuania)
Thiophanate-methyl (Lithuania)
Penthiopyrad (Lithuania)
Fenpyroximate (Lithuania)

Spirotetramat (Lithuania)

Fluopyram, Tebuconazole (Lithuania)

Methoxyfenozide (Lithuania)

Plant oils/ Rape seed oil, Pyrethrins (Luxemburg)

Cydia pomonella Granulovirus (CpGV) (Luxemburg)

Metarhizium brunneum strain Cb15-III (Luxemburg)

Isoxaben (Latvia)

Triflusulfuron (Latvia)

Propyzamide (Latvia)

Carbetamide (Latvia)

Oxadiazon (Portugal)

Paclobutrazol (Portugal)

Tebuconazole (Portugal)

Spiromesifen (Portugal)

Phosmet (Portugal)

Alpha-Cypermethrin (aka alphamethrin) (Portugal)

Clothianidin (Portugal)

Spinosad (Slovenia)

Alpha-Cypermethrin (aka alphamethrin) (Slovenia)

Desmedipham, Ethofumesate, Lenacil, Phenmedipham (Slovenia)

(E,E)-8,10-Dodecadien-1-ol, Dodecan-1-ol,Tetradecan-1-ol (Slovakia)

(E,Z)-7,9-Dodecadien-1-yl acetate, (Z)-9-Dodecen-1-yl acetate (Slovakia)

Dimethenamid-P (Slovakia)

Potassium hydrogen carbonate (Slovakia)

Imazamox, Pendimethalin (Slovakia)

Potassium hydrogen carbonate (Slovakia)

Copper hydroxide (Slovakia)

Propaquizafop (Slovakia)

Fatty acids C7-C18 and C18 unsaturated potassium salts (CAS 67701-09-1) (Slovakia)

Propaquizafop (Slovakia)

Copper oxychloride (United Kingdom)

The Committee took note of the notifications submitted by Austria, Belgium, Bulgaria, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Hungary, Lithuania, Luxemburg, Latvia, Portugal, Slovakia, Slovenia and The United Kingdom.

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

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

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

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

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

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

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

EFSA reported about the status of implementation of the Pesticide Steering Network (PSN) Action Plan: the final documents concerning the accordance check (guidance plus checklist) will be presented to the PSN at the meeting in June. In order to assure a proper implementation in the long term, EFSA will include these documents into a more comprehensive Practical Guidance to be discussed and noted by the Committee.

EFSA is concerned about a lack of quality in some Assessment Reports. EFSA was also approached by some applicants with the intention of submitting additional studies after EFSA identified concerns late in the process. In order to avoid late data requests EFSA strongly recommended all rapporteur Member States to contact EFSA as soon as potential concerns are identified during the assessment.

EFSA updated on the adoption of the opinion on baby food, the publication of the statement on Diquat and several ongoing public consultations.

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

The presentation on the Harmonised Risk Indicators, which was announced for the May meeting, is postponed to July.

A.14 Report from working groups:

1. Plant Protection Products Application Management System (PPPAMS)

   No news.

2. Working group on Biopesticides

   No new meeting since last SCPAFF.

3. Working group on Seed Treatments (no update)

   No new meeting since last SCPAFF.

4. Working Group on Co-formulants

   Postponed; a more comprehensive update will be given in July.

A.15 OECD:

1. Coordination for the WGP

   The Commission informed the Member States about the meetings that will take place at the OECD between 18-22 June and highlighted a few events organised before the working group pesticides and encouraged Member States to pay attention to several ongoing surveys launched by OECD. It was announced that a coordination teleconference with participating Member States and EFSA would be organised on 5 June.

A.16 Court cases:

Judgements by the General Court for T-429/13, T-451/13 and T-584/13 (neonics and fipronil cases)

The Commission gave a short update on the content of the cases.

A.17 Endocrine Disruptors:

1. Implementation of the new ED Criteria renewal active substances:

   – date of application;

   The Commission informed that the criteria for biocides will become applicable on 7 June 2018 and those for PPP on 10 November 2018. It was clarified that, although the draft submitted to the Official Journal was correct, an error occurred during publication and the date of application appearing in the legal text was incorrectly 20 October 2018. Considering that the vote had been taken with the indication of the correct application date of 10 November 2018, a corrigendum has been published on the Official Journal. The link to the corrigendum is also available on the SANTE ED website.

   Following a comment from a Member State, it was clarified that, although the interim criteria are applicable until 9 November 2018, EFSA and Member States could already start assessing ED properties according to the new ED criteria and the ED guidance expected to be published on 7 June 2018, for those assessments for which the DAR/RAR and/or the EFSA Conclusions will be submitted from 10 November 2018 onwards, as the new ED criteria will become applicable by that date.

– amending Implementing Regulation 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties

The Commission explained the main changes which need to be introduced into the draft act with respect to the version already discussed in the previous meeting. The revised draft act will be uploaded on CIRCA BC as soon as the internal consultation of the Commission services is finalised. Member States will be informed and asked to provide their comments.

2. Draft EFSA/ECHA guidance document:

– risk manager consultation and future guidance adoption under Article 77 of Regulation (EC) No 1107/2009

The Commission informed that Member States (risk assessors) had been consulted on the draft guidance document from 16 April to 27 April 2018. Based on the comments received, a revised guidance document was again circulated to Member States (risk managers) on 15 May 2018 together with the comments received previously from risk assessors, including how they had been considered. The risk managers' consultation will be closed on 25 May 2018.

After consideration of this last round of comments, a final review of the guidance will be adopted and published by EFSA and ECHA on their websites on 7 June 2018. The publication in the EFSA Journal is expected a few weeks later, together with the technical report providing the details of the consultations.

The intention is to table the ED guidance at the next Committee meeting in July for noting/adoption. The specific procedures for adoption are still under discussion with the Commission Legal Service.

One Member State asked to mention in the guidance that "presumed EDs" are identified and also asked that the guidance is adopted as soon as possible and that a review is planned in the near future.

One Member State asked EFSA and ECHA to ensure effective communication in order to ensure coherent assessments in the BP and PPP sectors.

One Member State reminded the Commission of its commitment to table the draft to amend the provision on negligible exposure as soon as the criteria will be adopted. The Commission indicated that it intends to table that draft for discussion at the next Committee meeting in July.

A.18 Minor Uses.

A meeting of the Minor Uses Steering Group was held on 4 April 2018, followed by a meeting of the extended Steering Group on 5 April 2018, which was open to all funders.

Regarding the long-term funding strategy Member States have been approached in November 2017 with a request for voluntary assessed contribution. Positive responses had been received from 13 EU Member States and Switzerland. Funding is still assured for 2018, for the year 2019 and beyond the situation is still unclear.

A.19 Interpretation issues:

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

The Commission suggested to decide as follows:

a) Lava meal (BE)

Effect of lava meal on fungal pests is of physical nature whereas the repellent effect on insects is of unspecific nature. Therefore, lava meal is considered not to be a plant protection product (PPP).

b) Salvis freeze (BE)

After application, the product forms a polymeric grid structure which covers the pest and immobilizes it. This effect is purely physical and the substance does not interact with the metabolism of the pest, it is not considered a PPP.

c) Straw pellets (BE)

The substance is used as a groundcover. The presence of iron sulphate, which is an approved active substance with anti-moss action, combined with the claim against mosses leads to conclude that this product is a PPP.

d) Moss control / fertilizers (DK)

In some Member States there are products on the market which contain iron at a concentration which is considered effective against mosses but which are not authorised as plant protection products. Mostly, these products are declared as fertilizers, in some cases with a claim of an anti-moss side-effect, in some cases with more unspecific claims (e.g. "makes the lawn greener"). The Commission insisted that all such products are to be considered PPP and require an authorisation as PPP.

e) Uses against lichens on trees (AT)

As lichens are not considered as unwanted plants and the reason for using the product seems to be rather a cosmetic one than effectively protecting the trees in question, these uses are not considered to be PPP uses.

f) Biodegradable Mulch Film (FI)

The fluidic mulch has a complex composition and it hardens after application. However, due to the presence of acetic acid, which is approved as an active substance with herbicidal effect, the mulch film is considered to be a PPP.

Member States were invited to indicate their agreement/disagreement before 29 June.

The Commission updated Member States about the pending borderline cases and informed about a new one (mulch) inviting them to provide their comments and interpretation by 8 June 2018.

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

1. Status of harmonised classifications

An updated table with the status of classifications under consultation 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
3. Report on the alignment of the classification and peer-review processes

A.21 Glyphosate.

The Commission asked once again whether any Member State or group of Member States would be ready to become RMS for the next renewal. No Member State volunteered.

A.22 PEST Committee.

The Commission informed the Committee about the three meetings of the PEST Committee that had already taken place (on 12/04 with representatives from the Commission and EFSA; on 26/04 with the competent authorities of France, Sweden and the United Kingdom and on 15/05 with BfR, the Julius Kühn-Institut, the NGO Global 2000 and ECPA) and about the next two meetings of the Committee on 7 June (with SAM, EFSA, ECHA and Mr Portier) and on 19 June (with Commissioner Andriukaitis, OECD, the European Ombudsman and Ms Geissen from the Agriculture University Wageningen).

The Commission also informed that verbatim records of the meetings will be available on the Parliament's website, starting with the meeting on 15/05: first in the original languages in which the interventions were made, and later on translated into English.

A.23 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

No point to be raised.

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).

The Commission informed about the Second Workshop held on 16 May where Member States, EFSA, stakeholders and the Commission attended. The preliminary findings were presented by the contractor conducting the external study and discussed together with the participants. The main points discussed were the number of active substances available versus the uses they cover, the use of emergency authorisations and the impact on human health and environment, and issues concerning minor uses.

The Commission informed that the external study is expected to be finalised during summer. The final report (Staff Working Document) that will be drafted by the Commission services will accompany a report that is expected to be presented to the European Parliament and to the Council during the first half of 2019.

A.25 Information concerning Brexit.

No news on Brexit to be raised under this point.

A.26 Draft Commission Notice concerning a list of potentially low-risk substances (state of play).

The Commission informed that the interservice consultation has been finalised, the act will be translated in all languages and will be adopted and published likely before summer. The progress report on the implementation plan on low-risk substances and products and the adopted Commission Notice cannot be presented to the Council under the Bulgarian Council Presidency anymore and will probably be postponed to the Austrian presidency.

A.27 Scientific publications and information submitted by stakeholders.

All documents submitted by stakeholders before the meeting had been made available to Member States.

A.28 Confirmatory data pending and renewal ongoing – Clofentezine and Difeconazole (RMS ES).

Postponed.

A.29 Commission Regulation (EU) No 547/2011: notification of additional phrases by Member States and follow-up of MAgPIE project.

The Commission informed about its intentions to follow-up the MAgPIE (Mitigating the risks of Plant Protection Products in the Environment) project.

First action would be to update Annexes II and III of Regulation (EU) No 547/2011 as regards labelling requirements. Member States were therefore invited to provide the additional Safety Precaution Phrases of application at national level. Deadline for this reply was set at 15 June.

Furthermore, the Commission explained that an action plan would be elaborated with the help of a new Steering Committee to be set up with Member States, industry and NGOs to pilot the actions and create relevant expert groups dealing with specific topics or within a given geographical zones. Deadlines for providing names of candidates for both the Steering Group and future working groups was set at 8 June.

A.30 Date of next meeting.

The next regular meeting will take place on 19 and 20 July 2018.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the low-risk active substance *Pasteuria nishizawae* Pn1, 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/10160/2018 rev. 0.1).

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 oxasulfuron 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/10886/2017 Rev.1).

The Commission shortly presented the reasons for the proposed non-renewal. The Commission indicated that alternative herbicidal active substances are still approved at EU level (e.g. glyphosate, carfentrazone and pyraflufen) but that a complete overview of alternatives is not available to the Commission as the formulated products are authorised at Member State level.

Given the risks and the high number of data gaps identified, the Commission considers that the nature of the (potential) risks overrule the economic considerations, also taking into account the available alternatives mentioned above.

The Commission indicated that Member States have furthermore the option to consider if the use of oxasulfuron is indispensable for certain uses. If so, Member States may grant emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 for a maximum of 120 days. However, Member States must respect all conditions in that Article and emergency authorisations must be duly justified.

Vote postponed

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance *Ampelomyces quisqualis* strain AQ10, as a low risk active 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE-10210-2018 Rev.1)

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance diquat, 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 Review Report SANTE/10396/2016 Rev.2).

The Commission shortly presented the changes in revision 4 of the draft Regulation. The Commission indicated that alternative herbicidal active substances are still approved at EU level (e.g. glyphosate, carfentrazone and pyraflufen) but that a complete overview of alternatives is however not available to the Commission as the formulated products are authorised at Member State level. The Commission reminded the Member States of the many letters of support from stakeholders received which discussed mainly the necessity of the desiccant use (pre-harvest) on potatoes but also the importance of other uses such as for hops, peas, beans and linseed.

It is therefore understood from these letters of support that a non-renewal of diquat might have an economic impact on the potato sector as it is widely used as desiccant mainly to prevent transmission of plant pathogens.

But given the risks and data gaps identified in the risk assessment, the Commission considers the nature of these risks to overrule these economic considerations, also taking into account the still available alternatives mentioned earlier.

The Commission indicated that Member States have furthermore the option to consider if the use of diquat is indispensable for certain uses. If considered indispensable for a certain use, Member States may grant emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 for a maximum of 120 days. However, Member States must respect all conditions in that Article and emergency authorisations must be duly justified.

One Member State made a statement regarding the importance of diquat as a dessicant in potatoes but given the risks identified supported the proposal for non-renewal of the approval for diquat.

Vote taken: No opinion.

Reasons for abstention/negative opinion:

- Diquat is essential for agriculture and considering risk mitigation options (e.g. bufferzones and drift reducing nozzles) are available.
- Importance of the substance for local agriculture and the lack of alternatives.
- Importance of diquat for certain crops.
- Not sufficient time to study the latest EFSA statement
- Availability of risk mitigation measures.
- Risk assessment considered too conservative.
- Importance of the substance for the use in hops and potatoes.
- The safe use to bystanders and residents has been identified with the German model using default input parameters and a buffer zone and indicated that the risk to birds should be addressed at Member State level.

As a consequence, the Chair informed the Committee that the draft Regulation will be submitted to the Appeal Committee.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance trifloxystrobin, 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/10107/2018 Rev.2)

The renewal proposal was presented. Following the request of one Member State, the Commission specified that, although the minimum purity and the maximum level of a relevant impurity have been modified with respect to the original approval conditions, the general reference specifications are not changed.

Vote taken: Favourable opinion.

Reasons for abstention/negative opinion:

- Potential leaching of metabolites in groundwater.
- Confirmatory data on endocrine disruptors should have been requested.
- Trifloxystrobin is proposed for classification as toxic for reproduction category 2 and risk to groundwater.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance fenpicoxamid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10319/2018 Rev.1).

Due to the delay in finalising the interservice consultation, the final draft could not be presented for a vote. It was expected that this would be possible in the meeting of the Committee in July.

Vote postponed

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance pethoxamid 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/11635/2017 Rev.0.1).

Due to the delay in finalising the interservice consultation, the final draft could not be presented for a vote. It was expected that this would be possible in the meeting of the Committee in July.

Vote postponed

B.08 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 fenamidone, 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/11004/2016 Rev.2).

The Commission presented the final drafts of the renewal report and Regulation concerning non-renewal of approval. The Commission recalled that letters from growers received previously had indicated that the loss of fenamidone could impact the number of different substances available to manage resistance development. The Commission indicated that according to the information available alternative fungicidal active substances are still approved at EU level but that a complete overview of alternatives is not available to the Commission as the formulated products are authorised at Member State level.

However, given the risks and concerns identified during the EU review, the Commission considers that the nature of those risks overrule the economic considerations, also taking into account the available alternatives mentioned above.

The Commission indicated that Member States have furthermore the option to consider if the use of fenamidone is indispensable for certain uses. If so, Member States may grant emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 for a maximum of 120 days. However, Member States must respect all conditions in that Article and emergency authorisations must be duly justified.

Vote Postponed

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance carfentrazone-ethyl in accordance with Regulation (EC) No 1107/2009 of the European Parliament and 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/10144/2017 Rev.6).

The final draft of the renewal report and Regulation were presented.

Vote taken: Favourable opinion.

Reasons for abstention/negative opinion:

- Potential leaching of metabolites in groundwater.
- Potential risk for aquatic organisms and algae.
- Carfentrazone-ethyl is proposed for classification as carcinogenic category 2.

B.10 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 pymetrozine, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/00103/2015 Rev.4).

The Commission briefly recalled the reasons for the proposed non-renewal. Some Member States intervened to indicate that they considered there was potential for an acceptable use on oilseed rape when used once every 3 years.

The Commission indicated that letters had been received in support of continued approval of pymetrozine from growers in different Member States concerning different crops (e.g. oilseed rape, sweetcorn, herbs, cucumbers). From these letters of support it is understood that a non-renewal of pymetrozine might have an impact on the tools available for growers to manage the development of resistance in aphids and other pests, and also the ability to operate IPM solutions. For the use on oilseed rape the restrictions of the use of neonicotinoids has also reduced the available chemical tools available to control pollen beetle. However, some alternative active substances are still approved at EU level but that a complete overview of alternatives is not available to the Commission as the formulated products are authorised at Member State level.

Given the risk to groundwater from exposure to relevant metabolites and the other deficiencies identified, the Commission considers that the nature of those risks and deficiencies overrule economic and other impacts, also taking into account the available alternatives mentioned above.

The Commission indicated that Member States have furthermore the option to consider if the use of pymetrozine is indispensable for certain uses. If so, Member States may grant emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 for a maximum of 120 days. However, Member States must respect all conditions in that Article and emergency authorisations must be duly justified.

Vote postponed

B.11 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 thiram, 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/11020/2017 Rev.3).

The Commission gave a brief update on recent developments with the file explaining that the applicant had withdrawn support for renewal of foliar uses. The Commission explained that this did not change the draft since the use as seed treatment also had concerns that precluded renewal, in particular but not only the high risk to birds and mammals (and discussions had in any case focussed on this use) but that due to this development there was a need to consider drafting changes to the drafts already presented to the Committee.

The Commission also outlined that the European Seed Association (ESA) had again written to the Commission to outline concerns about the loss of thiram for seed treatment.

The Commission also recalled previous letters that had been received in support of continued approval of thiram. From these letters of support it is understood that for some cases there may be alternative substances that could replace the use of thiram (individually or in combination) whilst in other maybe not. It appears that alternatives would be more expensive than thiram. The ESA indicate that there would be a reduction in crop production due to 'damping off' of the seedling. ESA and some others also highlighted that the use of thiram is a phytosanitary requirement for some third countries and that the treatment of seeds will move outside of the EU.

For the particular uses of thiram as a fungicide seed treatment, alternative active substances are still approved but a complete overview of alternatives is not available as the formulated products are authorised at Member State level.

However, the Commission considered that the risks and issues identified overrule the impact of possible loss of the substance for resistance management and also any economic impact, also taking into account the alternatives still available.

The Commission indicated that Member States have furthermore the option to consider if the use of pymetrozine is indispensable for certain uses. If so, Member States may grant emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 for a maximum of 120 days. However, Member States must respect all conditions in that Article and emergency authorisations must be duly justified.

Vote postponed

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation as regards the extension of the approval periods of the active substances fenbuconazole, metosulam, pyridaben, quinmerac, triflumuron and zinc phosphide amending the Annex to Implementing Regulation (EU) No 540/2011.

Vote taken: Favourable opinion.

Reasons for abstention/negative opinion:

- The draft Act includes one active substance which should be evaluated without delay.

B.13 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation as regards the extension of the approval periods of the active substances alpha-cypermethrin, *Ampelomyces quisqualis* strain: AQ 10, beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, carfentrazone ethyl, carvone, chlorpropham, cyazofamid, desmedipham, dimethoate, dimethomorph, diquat, ethephon, ethoprophos, etoxazole, famoxadone, fenamidone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, *Gliocladium catenulatum* strain: J1446, isoxaflutole, metalaxyl-m, methiocarb, methoxyfenozide, metribuzin, milbemectin, oxasulfuron, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, pymetrozine, s-metolachlor and trifloxystrobin amending the Annex to Implementing Regulation (EU) No 540/2011.

Vote taken: Favourable opinion.

Reasons for abstention/negative opinion:

- The draft Act includes active substances which should be evaluated without delay.

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Notice – Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009.

The Standing Committee was informed that the discussion in the Commission was not finalised, especially regarding the possible reference to Article 77 of Regulation (EC) No 1107/2009. The document will be presented the meeting of the Committee in July.

Vote postponed