EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2018)6172585

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 19 JULY 2018 - 20 JULY 2018

(Section *Phytopharmaceuticals - Legislation*)

CIRCABC Link: *https://circabc.europa.eu/w/browse/8883e640-675b-4602-b7c2-acddf97d5125*

A.01 Summary Report of previous meetings.

The Commission informed that the outstanding summary records of previous meetings of this section of the Standing Committee will be published soon.

A.02 New active substances:

1. New admissible dossiers to be noted

   Three new admissible dossiers were noted as follows:

   a) Metyltetraprole, a fungicide applied for by Sumitomo. The rapporteur Member State is France and the admissibility was reported to the Commission on 23 May 2018.

   b) *Trichoderma atroviride* AGR2, a fungicide applied for by Agrolor. The rapporteur Member State is France and the admissibility was reported to the Commission on 5 June 2018.

   c) Isoflucypram, a fungicide applied for by Bayer. The rapporteur Member State is the United Kingdom and the admissibility was reported to the Commission on 11 May 2018.

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

   a) Bacillus subtilis IAB/BS03

      The Commission summarised that the EFSA Conclusion did not identify any area of concern, but that 3 issues could not be finalised. Drafts of the review report and the Regulation are intended to be available for the next meeting. Member States were invited to submit comments by 3 September 2018.

   b) Asulam-sodium

      The Commission summarised the three areas of concern identified (birds and mammals, consumers, and potential endocrine disrupting properties) and that the applicant had indicated that additional data are available which were not considered in the EFSA Conclusion. Some uses of the active substance may qualify for Article 4.7 derogation (e.g. for bracken control). Depending on submission of relevant information by the applicant and subject to the views of Member States, EFSA may be mandated to issue an addendum to its

conclusion. Member States were invited to submit comments by 3 September 2018.

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play

   a) AIR III

   b) AIR IV

   The Commission presented the state of play of the renewal programmes AIR III and AIR IV.

   In the AIR III programme 19 active substances are no longer supported. For 14 of those, approval has already expired while the approval of glufosinate expires on 31 July 2018 and for chloridazon, imazaquin, oxadiazon and quinoclamine approval expires by 31 December 2018.

   The Commission raised concerns about delays in the scientific evaluations by Member States and reminded Member States of their obligation to respect the legal deadlines and submit their assessments on time. The Commission urged Member States to speed up ongoing assessments that are delayed, in particular for substances that may fail to satisfy the approval criteria.

   The Commission thanked all Member States who are using the functional mailbox (sante-pesticides-renewal-of-approval@ec.europa.eu) for all issues concerning renewals and reminded about the importance to keep the functional mailbox in copy of all correspondence in order to ensure business continuity.

   The Commission also reminded Member States of their obligation under Article 60 of Regulation (EC) No 1107/2009 as regards the availability of the list of studies relied upon for the renewal of active substances. Early availability of these lists is crucial to ensure an efficient process of renewal of authorisations of plant protection products containing active substances the approval of which has been renewed.

2. Exchange of views on EFSA conclusions:

   a) Rimsulfuron

      The Commission summarised the EFSA Conclusion, highlighting a critical concern for one of the metabolites, found in ground water above the 0.1µg/l parametric drinking water limit in all scenarios. It was not possible to conclude on the genotoxic potential of this metabolite due to some weaknesses of the studies provided. In addition, as this metabolite is not a major one, it was not possible to derive the reference value from the parent compound. As the risk assessment could not be concluded because of these issues, a non-renewal is likely to be proposed. Comments had been received from the applicants. Member States were invited to send their comments on the key points of concern highlighted by the EFSA conclusion by 3 September 2018. A draft review report will be presented at the next meeting of this Committee.

   b) Tolclofos-methyl

      The Commission reported about additional information submitted by the applicant as regards the EFSA Conclusion. Member States were invited to

submit comments by 3 September 2018. A draft review report will be presented at the next meeting of this Committee.

c) Dimethenamid-P

The Commission summarised the critical areas of concern identified in the EFSA Conclusion as regards the technical specification (which could be resolved) and the potential genotoxicity of one metabolite. The Rapporteur Member State indicated that they would comment on the EFSA Conclusion and the further position papers sent by the applicant. Member States were invited to submit comments by 3 September 2018. A draft review report will be presented at the next meeting of this Committee.

d) Spinosad

The Commission invited Member States to submit comments on the EFSA Conclusion by 3rd of September.

3. Draft Review/Renewal Reports for discussion:

a) *Beauveria bassiana* PRI 5339

Postponed.

b) Mecoprop-P

The Commission informed that comments had been received from the applicant on the draft renewal report proposing non-renewal of mecoprop-P. Comments had also been received from some Member States. A meeting had been held with the applicant. The concerns identified could not be solved. The Commission will proceed with the finalisation of the draft Regulation and the draft renewal report. Member States were invited to submit additional comments or views by 3 September 2018.

c) Desmedipham (short update)

Postponed.

d) Phenmedipham (short update)

Postponed.

e) Ethoprophos

Member States were invited to submit comments on the draft review report made available to Member States ahead of the meeting by 3 September 2018.

f) Trinexapac-ethyl

Postponed.

A.04 Confirmatory Data:

1. Dithianon (short update only)

The WTO-TBT notification process for the amendment of the approval conditions, based on the EFSA conclusion on the confirmatory data, is finalised. The comments received will be answered. The applicant had also sent some comments on the notification, which were the same as already submitted before. In the meantime, the applicant has sent the results of a new study that is supposed

to lift the outstanding issues. The Commission is waiting for the assessment from the Rapporteur Member State of this new information before proceeding further.

2. Iprovalicarb (review report to be noted)

   The Committee took note of the amended Review Report to finalise the confirmatory data procedure. One Member State did not take note since they did not support the renewal of the approval at the time when it was voted, and on that basis could not support any further update. The revised review report will be uploaded to the EU Pesticides Database in due course.

3. Urea (review report to be noted)

   The Committee took note of the amended Review Report to finalise the confirmatory data procedure. The revised report will be uploaded to the EU Pesticides Database in due course.

4. Isofetamid (short update only)

   Postponed.

5. Tea tree extract (short update only)

   Postponed.

6. Bupirimate (short update only)

   Postponed.

A.05 Article 21 Reviews.

Standing agenda point. No items to discuss.

A.06 Amendment of the conditions of approval:

1. New admissible dossiers to be noted:

   Standing agenda point. No items to discuss.

2. Exchange of view on EFSA conclusions:

   Standing agenda point. No items to discuss.

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

   Standing agenda point. No items to discuss.

4. SCLP new compounds belonging to the approved group:

   a) Draft review report rev.14 to include (8Z)-tetradec-8-en-1-yl acetate (to be noted)

      The revised review report had already been presented at the meeting of this Committee in May 2018. The Committee took note of the revised review report, which added two new SCLP compounds. The revised report will be uploaded to the EU Pesticides Database in due course.

A.07 Basic substances:

1. *Quassia amara* L. wood extract

   The Commission summarised that the EFSA Technical Report adopted in February 2018 points to data gaps that the applicant is now addressing via

a public-private funding initiative. Nevertheless, the Commission should comply with the legal obligation to present a draft decision within 6 months, which based on the available data would have to be negative. However, the applicant may re-submit a supplemented new dossier, which would allow reassessment.

2. New dossiers received (only for information)

   a) clayed charcoal (extension)

      Postponed.

   b) sodium hydrogen carbonate (extension)

      The Commission explained the intention of a company to propose an extension for use as post-harvest treatment of citrus through electrolysis of the basic substance: the application rate is falling within the range of the approved use (GAP) for this basic substance. A dossier would have to be prepared by the company as a basis for this extension.

      EFSA informed that the dossier for approval as active substance (not basic substance) is currently processed and would make the application as basic substance not admissible.

      A general discussion took place about situations where a basic substance has been approved while a dossier for active substance approval is submitted subsequently and vice versa. A state of play will be presented by the Commission at the next Committee meeting to discuss how to proceed.

   c) *Salix* spp. (extension)

      Postponed.

   d) sunflower (extension)

      Postponed.

3. Exchange of views on EFSA Technical Reports

   Nothing to report.

4. Draft Review Reports for discussion:

   a) Vinegar extension

      Postponed.

A.08 Guidance Documents:

On request by Member States, the Commission clarified the choice of issuing guidance documents in the form of Commission Notices without referring to Article 77 of Regulation (EC) No 1107/2009.

Although Article 77 of Regulation (EC) No 1107/2009 provides that the Commission may adopt guidance documents in accordance with the advisory procedure, it cannot be relied upon for the adoption of *non-binding* guidance.

Against this background and taking account of the previous practice regarding guidance documents under Regulation (EC) No 1107/2009, the Commission considers it appropriate to adopt new pieces of guidance in the form of Commission Notices. These are interpretative communications from the Commission. While not being

binding, the notices are generally published in part C of the Official Journal of the EU and therefore ensure a high level of transparency.

The Commission will continue the practice to prepare all guidance documents in close cooperation with the responsible working groups and the Standing Committee, and seeking the widest possible support from Member States.

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 Committee that the draft revised guidance document needs to be edited before going through the interservice consultation. It intends to discuss the revised document during the meeting of this Committee in October before its adoption as Commission Notice.

1. 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 Committee that the draft revised document has been edited and will undergo the interservice consultation in the coming days. It intends to discuss the revised document during the meeting of this Committee in October before its adoption as Commission Notice.

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 Committee that the draft revised document has been edited and will undergo the interservice consultation in the coming days. It intends to discuss the revised document during the meeting of this Committee in October before its adoption as Commission Notice.

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

   The Commission presented revision 5 of the Commission Notice regarding the implementation plan for the Bee Guidance Document. The wording of the Notice will be aligned with other Commission Notices.

   One Member State indicated that the EFSA Bee guidance document needs to be revised to take into account recent scientific developments. EFSA indicated that it does not consider it currently the right time to revise the Bee Guidance Document but that this can be discussed with the Commission as soon as new models become available.

   On request of a Member States, the Commission repeated its earlier explanation that a Commission Notice is not legally binding. One Member State indicated that Article 36(1) of Regulation (EC) No 1107/2009 obliges Member States to use guidance documents available at the moment of application.

   Member States were invited to inform the Commission regarding their support of the Commission Notice by 3 September 2018.

4. 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 be noted)

The European Commission presented the last draft version (version 3 of revision 5) of the revised guidance document, provided by two lead Member States. Another Member State and EFSA had submitted additional comments and all the comments had been addressed.

The note taking of the revised guidance document was postponed because of late comments from a Member State. The Commission will carefully check with the two lead Member States for this revised Guidance Document and report to the Standing Committee in October.

5. Draft Commission Notice – Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009 (SANTE/10407/2018 Rev.3) – final consultation before adoption

   The European Commission presented a revised draft of the Commission Notice on the guidelines for data protection, on which the Interservice consultation was closed. One Member Stated submitted additional comments, which had already been submitted during the consultation in the Post Approval Issue Group.

   Considering these comments, the Commission invited Member States to submit additional comments by 20 August 2018.

   The Commission will carefully consider the late comments from Member States and may proceed with the formal adoption. The Commission will report to the Standing Committee in October.

   The Commission Notice will be published in the Official Journal and should be implemented 3 months after the date of publication.

6. Defining Specific Protection Goals for environmental risk assessment – update on next steps

   The Commission summarised its proposal for a step-wise approach for defining specific protection goals for environmental risk assessment. In a 1st step, agreement should be found in this Committee as regards the method to be used for defining specific protection goals. EFSA's outputs from 2010 and 2016 are proposed as basis for the method. Once the method is agreed, Specific Protection Goals could be defined. Stakeholders will be involved during this process.

   Member States were invited to submit comments or suggestions by 3 September 2018.

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

The Committee took note of 34 notifications submitted by Estonia to amend the conditions of approval of plant protection products containing glyphosate.

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

1. New notifications (to be noted)

   The Committee took note of 2 notifications submitted by Luxemburg.

   One Member States stated that it would like to be informed about the technical details underlying these notifications. It was agreed that the Member States

concerned would discuss this bilaterally and, if applicable, report to this Committee.

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

   Following an analysis of notifications under Article 36(2) it becomes clear, that the provisions are not applied by all Member States in the same way. In particular, mutual recognition was refused in several cases not because of the particular conditions in the recognising Member State, but because of a disagreement about the outcome of the risk assessment carried out by the reference Member State. The Commission has collected statements from affected reference Member States and will make them available to all Member States in order to allow an informed discussion in one of the future meetings.

3. On-board fumigation of grain

   No additional comments had been received since the last meeting. The Commission therefore considered the discussion closed.

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

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.

The Commission requested Member States to assure entering all information requested into the Plant Protection Application Management System, as this information is necessary to judge whether any such authorisation was granted according to the provisions of Article 53 of Regulation (EC) No 1107/2009. In particular, the Commission reminded Member States of the need to fully complete the fields to ensure that the Commission and others can understand the basis for the authorisation.

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, as it was done for some emergency authorisations granted for neonicotinoids (see subpoint 2).

One Member State commented that the existing Working Document on emergency authorisations (SANCO/10087/2013 rev.0) should be reviewed to take into account developments in the area and to provide more advice to applicants and Member States. The Commission explained that this was already being considered and that Member States would be consulted when a draft revised document would be available.

1. New notifications (to be noted)

The Committee took note of authorisations submitted in the PPPAMS by the Member States in the period from 15 May 2018 until 6 July 2018, as follows:

Number	Member State	Active Substance(s) in the Plant Protection Product authorised
2	EL	1,3-Dichloropropene
1	SI	2,4-D

		Florasulam
4	EL	Abamectin (aka avermectin)
1	SK	Acequinocyl
1	IE	Asulam
1	ES	Azoxystrobin
1	FR	Bacillus firmus I-1582
1	FR	Bacillus thuringiensis subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348
1	IT	Beauveria bassiana strains ATCC 74040 and GHA
1	RO	Beta-Cyfluthrin Clothianidin
1	SK	Bifenazate
1	EL	Boscalid (formerly nicobifen) Pyraclostrobin
1	SK	Bupirimate
1	BE	Carfentrazone-ethyl
1	NO	Chlorantraniliprole
1	ES	Chlorpyrifos-methyl
1	FR	Clomazone
1	SK	Clopyralid
2	AT	Copper hydroxide
2	FR	Copper oxychloride
1	BE	Cyantraniliprole
1	DE	Cyantraniliprole
1	FR	Cyantraniliprole
1	NL	Cyantraniliprole
1	SK	Cyantraniliprole
2	UK	Cyantraniliprole
1	EL	Cyclanilide Ethephon
1	EL	Cyclanilide Ethephon
1	NL	Daminozide
1	BE	Emamectin
1	SK	Emamectin
1	EL	Fenamiphos (aka phenamiphos)
1	ES	Fenpyroximate
2	PT	Flonicamid (IKI-220)
1	SK	Flonicamid (IKI-220)
1	ES	Fluopyram
1	ES	Fluopyram Trifloxystrobin
1	EL	Fosetyl
1	ES	Fosthiazate
2	ES	Gibberellic acid
1	AT	Hexythiazox
1	RO	Imidacloprid
1	FI	Iprodione

3	BE	Mancozeb
1	FR	Metalaxyl-M
1	ES	Molinate
1	BE	Pelargonic acid (CAS 112-05-0)
1	NL	Pepino mosaic virus strain CH2 isolate 1906
2	ES	Pyrethrins
1	PT	Pyrethrins
1	AT	S-Abscisic acid
1	FR	Sodium hypochlorite
1	FR	Spinosad
1	SK	Spinosad
1	ES	Spirotetramat
1	NL	Sulphur
1	RO	tau-Fluvalinate
1	LV	Thiacloprid
1	AT	Verticillium nonalfafae

2. EFSA Technical Reports on the_Art. 53(2) examination of emergency authorisations for neonicotinoid active substances

The Commission informed that, based on the 7 technical reports issued by the EFSA, it considered that 9 out of the 26 emergency authorisations evaluated were not justified. These emergency authorisations were granted by Romania, Hungary, Lithuania and Bulgaria. The Commission also informed that Commissioner Andriukaitis invited the responsible Minister in each of these Member States to confirm that these emergency authorisations will not be repeated. Available alternatives to restricted neonicotinoids are discussed in the EFSA technical reports.

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

1. Guidance on preparing good quality dossiers and Assessment Reports

EFSA informed about a draft document prepared in co-operation with experts of some Member States, which aims at improving the peer review process. The draft is currently being commented by risk assessors from the Member States and discussions are progressing.

2. General update

Further, EFSA updated on the alignment with the ECHA processes for harmonised classification and labelling under the CLP Regulation, the new independency policy of EFSA, the last outcomes of the PPR Panel with the new Panel being operational since July 2018. EFSA highlighted the on-going public consultations on genotoxicity assessment of chemical mixtures and MIXTOX guidance, as well as the call for data launched to update the guidance on exposure. The final Guidance document for endocrine disruptors has been published in the EFSA Journal.

A.13 News from Health and Food Audits and Analysis (SANTE, Directorate F, former FVO):

1. Legal basis for controls on the marketing and use of plant protection products under Regulations (EC) No 882/2004 and (EU) No 2017/625.

The Commission summarised the approach to outstanding audit recommendations relating to the alignment of official controls on the marketing and use of plant protection products with Regulation (EC) No 882/2004: these audit recommendations will now be closed as this Regulation is superseded by Regulation (EU) No 2017/625. Member States were reminded to align their controls for the marketing and use of plant protection products with Regulation (EU) No 2017/625.

2. General update – no news.

A.14 News from Sustainable Use Directive (Directive 2009/128/EC).

The Commission summarised the outcome of the most recent SUD Working Group meeting, held on 20-21 March 2018:

- The Commission plans to respond to all Member States as regards their responses to the Commission letter to each Member States on the quality of their NAPs.
- The draft harmonised risk indicator was discussed and Member States broadly supported the principle of a harmonised risk indicator.
- Updates on low risk active substances, European Innovation Partnerships, water quality, pollinators, and recording of pesticide poisonings were given by the Commission and/or agencies.
- Member States were informed that the Commission is reflecting on the interpretation of the provisions under Article 5 of Directive 2009/128/EC.
- Member States were informed that pesticide application by drones is considered as aerial spraying and that the requirements of Article 9 of Directive 2009/128/EC must be met.
- A stakeholder (Pesticide Action Network, PAN) was invited and presented their work with regard to SUD and IPM. Other stakeholders will be invited to the next meetings.

A.15 Report from Working Groups:

1. Plant Protection Products Application Management System (PPPAMS)

   No discussion took place.

2. Working group on Biopesticides

   The Commission informed about the on-going discussions concerning (1) the draft guidance document on risk assessment of metabolites produced by microorganisms, (2) the draft guidance document on antibiotic resistance and (3) the draft guidance document dedicated to the inclusion of new active substances in the group of Straight Chain Lepidopteran Pheromones. Data requirements for biopesticides were also touched upon by the working group, for which the next meeting is scheduled for September.

3. Working group on Seed Treatments

   The Commission informed about new developments on the draft Guidance on Seed Treatments and thanked the experts from Member States for their valuable contribution. The Commission informed that the document will be opened for

Member State's and EFSA's comments until 30 September 2018. Stakeholders will also be consulted.

4. Working Group on Co-formulants

   Update postponed.

A.16 OECD:

1. Report of the Working Group on Pesticides (WGP) meeting (June 2018)

   The Commission reported about the WGP meeting held at OECD on 21/ 22 June. Issues covered were illegal trade, pollinators, harmonisation of dossier structures and renewal procedures among OECD Member Countries. In addition, possible future seminars were discussed, one on the risk assessment of double-stranded interfering RNA (dsRNAi) and one on risk reduction.

2. Report of the Expert Group on BioPesticides (EGBP) meetings (June 2018)

   The Commission reported about the EGBP seminar and meeting respectively held at OECD on 18 and 19 June. During the seminar, test methods for biopesticides and issues to consider when using test methods developed for chemicals were discussed. Indicators for use of biopesticides, test methods and data requirements, microbials, MRLs for biopesticides, were also discussed. In addition, possible future actions were discussed, based on the outcomes of the OECD-Kemi workshop of 2013. It was also agreed that the seminar of the EGBP will focus on genomics for biopesticides in 2019.

A.17 Court cases:

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

   The Commission provided information regarding the Commission's interpretation of judgments T-429/13, T-451/13 and T-584/13 of 17 May 2018.

   In addition, it informed the Committee of the orders of the President of the General Court of 22.6.2018, which dismissed the respective applications seeking suspension of the operation of Commission Implementing Regulation (EU) 2017/1496 of 23 August 2017 concerning the non-renewal of approval of the active substance DPX KE 459 (flupyrsulfuron-methyl) (T-719/17-R) and suspension of the operation of Commission Implementing Regulation (EU) 2017/855 of 18 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance diflubenzuron (T-476/17-R). The Court considered that the applicants had failed to show the existence of serious and irreparable damage.

   The respective main applications remain to be decided.

   The Committee was also informed about a new court case, T-393/18, Mellifera vs Commission, seeking annulment of a Commission decision rejecting an application for internal review, under the Aarhus Regulation (Regulation (EC) No 1367/2006) of Commission Implementing Regulation (EU) 2017/2324 on the renewal of approval of the active substance glyphosate.

   The Committee was informed that a judgment on a pending case, T-12/17, brought by the same applicant for the annulment of a Commission decision

rejecting an application for internal review of Commission Implementing Regulation (EU) 2016/1056 on the extension of authorisation for glyphosate, is expected for the end of September 2018 and may have repercussions on the more recent case.

A.18 Endocrine Disruptors:

1. Draft Commission Notice - Implementation of Commission Regulation (EU) No 2018/605 under Regulation (EC) No 1107/2009: Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 (ECHA, EFSA, 2018)

   The Commission presented the draft Commission Notice and explained the editorial changes introduced with respect to the version presented at the previous meeting of this Committee, resulting from the outcome of the interservice consultation. On the basis of the comment of one Member State, a minor editorial change was agreed. The Commission will proceed with adoption and publication of the Notice.

2. Member States views on the draft Commission Regulation amending points 3.6.5. and 3.8.2. of Annex II to Regulation (EC) 1107/2009 taking into account current scientific and technical knowledge (SANTE_12011 2016, as discussed under point B.02 at the meeting the 21 December 2016)

   The Commission recalled its earlier commitment to discuss this document at this Committee once the ED criteria were adopted, and invited Member States to express their position as to whether they would support the document as it was presented in December 2016.

   The outcome of an indicative 'tour de table' was that 11 Member States would be in favour, 5 Member States against, 12 Member States would abstain or have currently 'no position', with some indicating they would have voted in favour in 2016 but currently have no mandate. The Commission concluded that at this point in time there is only very limited support, and invited in particular those Member States which have not expressed their position to inform about their positions by 3 September.

A.19 Minor Uses.

The Coordinator of the Minor Uses Coordination Facility (MUCF) informed that on 15 April 2018 the Grant Agreement with the European Commission regarding the funding of the EU Minor Uses Coordination expired. The MUCF is now fully depending on voluntary assessed contributions from Member States. Funds for 2018 are secured, but the situation for 2019 and beyond is unclear. As a consequence, the reimbursement policy of the MUCF will be changed (experts will only be reimbursed for travel and accommodation, and only a limited number of experts per Member State will be reimbursed).

In September 2018 all Member States will be approached by the MUCF for a voluntary assessed contribution for 2019 and will be asked for a commitment for the years after.

The priority list of minor uses needs has been updated and now includes minor uses needs of 26 Member States, including Norway and Switzerland. As a next step

companies will be actively approached to see if they have potential solutions (conventional, as well as biological) available or are in development.

A 'Guidance Document on Minor Uses' on the implementation of Article 51 and other provisions related to minor uses, is in preparation.

A.20 Interpretation issues:

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

   a) New entries in working document: Lava meal (BE), Salvis freeze (BE), Straw pellets (BE), Moss control / fertilizers (DK), Uses against lichens on trees (AT), Biodegradable Mulch Film (FI)

   The Committee agreed with the new entries (mentioned in the title) to the scope document. Some older entries will be checked for inconsistency and amended (e.g. lychens).

   Other entries not yet discussed will be re-opened at the next meeting (in-situ generation of ethylene and others).

   b) New case Frost Armour (FR)

   The Commission stated that the mode of action and composition of this application should be not considered as plant protection because it seems to be mainly offering a physical protection to frost.

   c) New case Palm tree Protector INO128 (FR)

   The Commission stated that the mode of action and composition of this application should be not considered as plant protection because it seems to be mainly offering a physical protection to insect attacks.

A.21 Classifications under Regulation (EC) No 1272/2008 / REACH:

1. Status of harmonised classifications

   An updated table on the status of submitted proposal for classification and labelling had been 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

   The Commission informed that the internal discussion on the draft Regulation was still on-going. Agencies are also consulted. The changes introduced now also cover a reshuffling of the deadlines for Rapporteur Member States and EFSA, giving them more time to perform their tasks. The finalised version of the draft Regulation is expected to be presented in October to this Committee.

   Member States were asked to inform their counterparts responsible for the CLP Regulation in the view of the discussions intended for October in this committee and at the next CARACAL meeting in November.

3. Report on the alignment of the classification and peer-review processes

   The Commission supported by EFSA reported on the on-going discussion between EFSA, ECHA and SANTE on the alignment of the assessments of proposals for harmonised classification & labelling (CLH) and peer-reviews.

Good practices have been identified from the very first cases where the joint template has been used. There is a need of close collaboration between competent authorities.

Member States were reminded that they are obliged to submit a CLH report or the joint template to ECHA where they challenge the existing classification in the RAR. A document is being drafted by the two agencies. It is planned to discuss it during the meeting of this Standing Committee in October.

A.22 PEST Committee.

The Commission informed about the meetings of the PEST Committee in the European Parliament that have taken place since May and informed about the upcoming meetings. The draft report of the PEST Committee is expected to be sent for translation on 18 September and a vote in the PEST Committee on the report is scheduled for December 2018.

A.23 Neonicotinoids.

On request of a Member State, the Commission reiterated that "permanent greenhouse" is defined in Regulation (EC) No 1107/2009, which states explicitly that greenhouses prevent release of plant protection products in the environment. Further, Recital 11 of Regulations (EU) No 2018/783 to 785 explains how the restrictions should be read as it states specifically that crops should not be replanted outside. Therefore 'entire life cycle' means until harvest of fruits, vegetables and cut flowers. It should be ensured that potted ornamental crops are not replanted outside.

Some Member States argued that potted ornamentals cannot be moved outside a greenhouse according to these Regulations. One Member State indicated that internal consultations are ongoing in their county regarding ornamental plants, as some genera are never planted outside in their country but some genera could be kept inside and outside. Two Member States argued that the restrictions are also applicable to imported ornamentals.

The Commission invited Member States to send further comments and/or suggestions on the need for potentially clarifying the wording of the restriction on the use of clothianidin, thiamethoxam and imidacloprid by 3 September 2018.

A.24 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

The Commission informed that the following outcomes of the PAFF Committee section Residues held on 13/14 June 2018, have possible impacts on authorisations of plant protection products:

Substance	Type of change (see above)	Agenda item	SANTE doc number
Diphenylamine	MRLs were lowered.	B 02	SANTE/10070/2018
Oxadixyl	MRLs were lowered.	B 02	SANTE/10070/2018
Penoxsulam	MRLs were lowered.	B 03	SANTE/10633/2017
Triflumizole	MRLs were lowered and the residue definition was	B 03	SANTE/10633/2017

	amended.		
Triflumuron	MRLs were lowered.	B 03	SANTE/10633/2017

A.25 Information concerning Brexit:

1. Re-allocation of ongoing assessments

The Commission proposed the designation of Member States as back-up for files currently processed by the UK (applications and other evaluations under Regulation (EC) No 396/2005 and 1107/2009). It outlined the approach and referred to the document on CIRCABC for the individual designations per file.

The Commission also stressed that this proposal had also been presented to the Standing Committee – section Residues in June 2018. Endorsement of the document is envisaged to take place at the meeting of this Standing Committee on 23/24 October 2018.

Three Member States raised concerns regarding the increased workload the re-allocation will imply. The additional work may lead to delays in delivering the scientific evaluations to EFSA.

Member States were invited to submit a reply coordinated with their representatives in the Standing Committee - section Residues by 24 August 2018.

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

The Commission informed that the Commission Notice is scheduled for adoption end of July, and will be published a few days after.

A.27 Data requirements and list of agreed test methods:

1. Update of the revision of the Communications (short update)

The Commission informed that the updated list of guidance documents and test methods for active substance and product dossiers was uploaded and open for comments by 3 September 2018. The first page of the draft Commission Communications have been uploaded too. Stakeholders will also be invited to comment on the updated draft Communications.

A.28 Commission Regulation (EU) No 547/2011:

1. Feedback about notification of additional phrases by MS

   The Commission thanked the Member States for their contributions that are currently processed in view of elaborating a proposal for additional harmonised safety precaution phrases. Regular reports of the state of play will be provided during the next meetings of this Committee.

2. Steering Committee, workplan and expert groups to follow-up on MAgPIE project.

   The Commission thanked the volunteering Member States for signalling interest in participating in the project on risk mitigation measures. The Commission informed about a recently started research project funded under Horizon 2020 (INNOSETA) which may be useful for the work envisaged.

A.29 Confirmatory data pending and overlapping with ongoing renewal – Clofentezine and Difeconazole (RMS ES).

The Commission explained that it is aware that in some instances a decision has not been taken to finalise the assessment of confirmatory data for substances where a renewal dossier has already been submitted. The Commission provided some initial thoughts on how to manage the situation but further reflections were ongoing.

In cases where the same data are provided as part of both processes or where the assessment of the data was completed and did not indicate any concern for the existing approval, the Rapporteur Member States for renewal should ensure that a full and comprehensive assessment of all data is undertaken during the renewal – reference may be made to an assessment of confirmatory data but the Rapporteur Member States should give their own view in the light of their renewal evaluation. In such cases the renewal may supersede the confirmatory data process.

In cases where confirmatory data were assessed but the process was not formally closed and during the renewal the Rapporteur Member States considers that the assessment of those data indicates a concern that needs to be addressed, the Rapporteur Member States should inform the Commission without delay.

A.30 Reference to significant impurities in List of Endpoints and Renewal Report (DE).

Postponed

A.31 Scientific publications and information submitted by stakeholders.

The Commission invited the Committee to consider the information submitted by stakeholders.

A.32 Date of next meeting.

The next meeting is planned for 23-24 October 2018, subject to final confirmation.

B.01 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. 2).

One Member State commented that the open point on processing was a concern for them but that overall they could support approval. Two Member States noted that they would not support the draft Regulation for this reason. The Commission explained that a rationale on this issue was included in the review report and that overall there was no concern for consumers but that in any case this point was included in the approval for Member States to pay attention to.

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 flurtamone, 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/11585/2016 Rev. 2).

The vote was postponed since the Commission had invited the applicant to comment on the renewal report considering that it had been amended following an updated EFSA Conclusion. Comments received would be duly considered.

Member States were asked to express their views and positions.

Vote postponed.

B.03 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 chlorpropham, 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/11966/2017 Rev. 2).

The Commission updated the Committee on developments since the meeting of the Committee in May including that:

The WTO-TBT notification procedure had ended and comments received from third countries were being replied to;

Letters from several growers' associations had been received expressing the need for chlorpropham;

Further comments and papers had been submitted by/on behalf of the applicants;

The EFSA Conclusion was being revised to correct the acute consumer exposure values since these were erroneously calculated after the expert meeting. The exceedance of the acute reference dose for chlorpropham and 3-chloroaniline would increase significantly but the overall outcome and concern is not expected to change;

The Commission updated the Committee on discussions with the applicant on two main issues: the use as herbicide and in particular the consumer risk assessment for the use on onions and lettuce, and the use of chlorpropham on potatoes as a sprout suppressant and the link with reducing exposure to acrylamide.

All Member States were asked for their positions and comments. Based on the feedback, the vote was postponed. The Commission agreed to reflect and to update Member States in the meeting of this Committee in October.

Vote postponed.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the approval of the basic substance Onion oil 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/10615/2018 Rev. 1).

The process was recalled and the vote took place on revision 1 of all documents.

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 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/11637/2017 Rev 0.2).

Reason for abstention/negative opinion:

- Concerns about the relevance and presence of groundwater metabolites.
- The restrictions considered not necessary as the subsidiarity applies.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation regards the extension of the approval periods of the active substances 1-decanol, 6-benzyladenine, aluminium sulfate, azadirachtin, bupirimate, carboxin, clethodim, cycloxydim, dazomet, diclofop, dithianon, dodine, fenazaquin, fluometuron, flutriafol, hexythiazox, hymexazol, indolylbutyric acid, isoxaben, lime sulphur, metaldehyde, paclobutrazol, pencycuron, sintofen, tau-fluvalinate and tebufenozide amending the Annex to Implementing Regulation (EU) No 540/2011.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation as regards the extension of the approval periods of the active substances 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, clomazone, cypermethrin, daminozide, deltamethrin, dimethenamid-p, diuron, fludioxonil, flufenacet, flurtamone, fosthiazate, indoxacarb, MCPA, MCPB, prosulfocarb, thiophanate-methyl and tribenuron amending the Annex to Implementing Regulation (EU) No 540/2011.

One Member State expressed concerns that the active substance chlorothalonil is in the act and would like reassurance that a draft Regulation proposing a non-renewal of the active substance is presented at earliest convenience. The Commission informed that the decision making process is ongoing and that there will be a discussion under agenda point C.09.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of Landes pine tar as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10109/2018 Rev. 1).

Vote taken: Favourable opinion.

C.01 Exchange of views of the Committee on the Commission Draft Review Report and Regulation concerning the approval of the active substance Flutianil 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/11948/2017) (short update only).

No new document was presented.

The Commission informed that an additional EFSA statement on the conclusion is available since 5 July. All former critical areas of concerns are addressed by the harmonised classification and all but one not finalised issues only relate to a subset of the uses supported by the applicant and are therefore not relevant for a decision whether or not to approve the substance. The only outstanding point is a remaining doubt whether the substance might have endocrine disrupting properties, although it is neither carcinogenic nor toxic to reproduction. This issue can only be finally addressed by assessing additional data in light of the new scientific criteria for endocrine disrupting properties. The Commission will decide how to move ahead and provide a revised draft as soon as possible.

C.02 Exchange of views of the Committee on the Commission Draft Review Report and Regulation concerning the non-renewal of approval of quinoxyfen 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 (SANTE/10213/2018 rev 1)(short update only).

The WTO-TBT notification procedure for the non-renewal had been launched. The Commission expected to present this draft Regulation for voting in the meeting of this Committee in October. Member States were invited to submit any comments by 3 September 2018.

C.03 Exchange of views of the Committee on the Commission Draft Review Report and Regulation renewing the approval of mepanipyrim 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/11620/2017 rev 5) (short update only).

The WTO-TBT notification procedure for the restriction to permanent greenhouses will soon be launched. The Commission expected to present this draft Regulation for voting in the meeting of this Committee in October. Member States were invited to submit any comments by 3 September 2018.

C.04 Exchange of views of the Committee on the Commission Draft Review Report and Regulation concerning the non-renewal of approval of etoxazole 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 (SANTE/10183/2018 rev 1) (short update only).

The WTO-TBT procedure for the non-renewal has been launched. The Commission expected to present this draft Regulation for voting in the meeting of this Committee in October. Member States were invited to submit any comments by September 2018.

C.05 Exchange of views of the Committee on the Commission Draft Review Report and Regulation renewing the approval of methoxyfenozide, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10295/2018 rev 1) (short update only).

The WTO-TBT notification procedure for the restriction to uses on fruiting vegetables of *Solanaceae* in greenhouse will soon be launched. The Commission is expected to present this draft Regulation for voting in the meeting of this Committee in October. Member States were invited to submit any comments by 3 September 2018.

C.06 Exchange of views of the Committee on the Commission Draft Review Report and Regulation concerning the approval of the active substance Metschnikowia fructicola strain NRRL Y-27328 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/10472/2018).

The Commission explained that two Member States had submitted comments in writing on the draft review report. One of the Member States is in favour of approving Metschnikowia as a low risk active substance and the other Member State enquired about the MRLs for Metschnikowia if approved as a regular active substance.

The Commission recalled the reasons why it did not propose to approve Metschnikowia as a low risk active substance and indicated that concerning the MRLs and an inclusion in Annex IV to Regulation (EC) 396/2005, a new wording had been proposed in the revised draft review report. The Commission encouraged Member States to liaise with their counterparts in the residues section of the Committee on the approach taken.

One Member State indicated that it had submitted comments on the draft review report in April and that it supported the Commission's intention not to approve the micro-organism as a low risk active substance. On the MRLs issue, it had not yet seen the revised version of the draft review report and could not comment.

Another Member State supported the inclusion of Metschnikowia in Annex IV to Regulation (EC) 396/2005 and invited the Commission to reconsider its position as it believes Metschnikowia complies with the criteria for low risk active substances.

The Commission invited Member States to submit comments by 3 September 2018 and indicated that it intended to vote in the meeting of this Committee in October.

C.07 Exchange of views of the Committee on the Commission Draft Implementing Regulation (EU) renewing the approval of the active substance copper compounds, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10506/2018).

The Commission presented the draft documents revised under consideration of the comments of one Member State and following the CIS.

The restriction of the application rate to 4 kg/ha/year was commented by some Member States which underlined the fact that the absence of a fully suitable environmental exposure assessment methodology led to overestimation of the risks to the environment. EFSA informed about the possibility to work (over a period of likely 2 years) on an adapted methodology to the specific case of copper to allow for a higher tier exposure assessment. Some Member States supported the restriction as proposed.

Some Member States considered that a 5-year renewal period is too short and suggested flexibility over a period of 5 years as regards the maximum application rate. The need to continue the monitoring of food contaminations and environmental contamination was also discussed, including the possibility to include copper in the human biomonitoring for EU project supported by the European Commission https://www.hbm4eu.eu/ .

The Commission expected to present this draft Regulation for voting in the meeting of this Committee in October. Member States were invited to submit any comments by 3 September 2018.

C.08 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance propiconazole, 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/11932/2017 Rev. 1).

The Commission explained that the WTO-TBT notification process was ongoing and due to end on 12 August 2018. The Commission is expected to present this draft Regulation for voting in the meeting of this Committee in October. Member States were invited to submit any comments by 3 September 2018.

C.09 Exchange of views of the Committee on a Commission Draft 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 Review Report SANTE/10186/2018 Rev. 0) (short update only).

The Commission presented the proposal and the comments received from the applicant and two Member States. The Commission explained why it considered the application of Article 4(7) of Regulation (EC) No 1107/2009 not appropriate.

One Member State underlined that the use of this substance is widespread, including many minor uses, and considers it a structural problem of Regulation (EC) No 1107/2009 that Article 4(7) is not applied in this case. Another Member State supported this and considered that the application of Article 4(7) is a risk-management decision.

One Member State supported the proposal but informed about lack of alternatives for the use in cereals.

The Commission invited Member States to submit their comments by 3 September 2018 and indicated that the vote might take place in the meeting of this Committee in December.

C.10 Exchange of views of the Committee on a Commission Draft 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 Review Report SANTE/10730/2018 Rev. 0) (short update only).

The Commission presented the draft and informed about an update of the conclusion on the peer review of the risk assessment by the EFSA with regard to the risk to bees. The Commission also summarised the comments received from the applicant.

The Commission invited Member States to submit their comments by 3 September 2018 and indicated that the vote might take place in the meeting of this Committee in December.

C.11 Exchange of views of the Committee on a Commission Draft Implementing Regulation (EU) amending Commission Implementing Regulation (EU) No 844/2012 in view of the implementation of Commission Regulation (EU) 2018/605 setting out scientific criteria for the determination of endocrine disrupting properties.

The Commission explained the modifications made to the current version of the document, based on previous comments by Member States in this Committee and the comments received via the interservice consultation. Few technical questions were raised. Member States were invited to send further comments by 27 August 2018. A vote during the meeting of this Committee in October is intended, after stakeholders have been consulted via the feedback mechanism.

C.12 Exchange of views of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance cyflumetofen.

The Commission informed the Committee that the interservice consultation had been launched to be followed by the WTO-TBT notification. A vote is foreseen in the meeting of this Committee in October.

C.13 Exchange of views of the Committee on a Commission Draft Implementing Regulation (EU) amending Implementing Regulation (EU) No 686/2012 as regards the rapporteur Member State and co-rapporteur Member State for the active substances glyphosate, lambda-cyhalothrin, imazamox and pendimethalin.

The Commission presented its initial reasoning for allocating the rapporteur and co-rapporteur Member States of the active substances glyphosate, imazamox and pendimethalin as well as a change in Rapporteur Member States of the active substance lambda-cyhalothrin for future renewal assessments.

Three Member States were not in favour of the proposal as regards glyphosate, with two Member States highlighting the issue of current and future resource constraints in their evaluating authorities which would make it difficult to handle the expected very high workload. One Member State agreed to the proposal to be co-Rapporteur Member State for glyphosate.

The Commission invited Member States to submit their comments by 3 September 2018 and reiterated the legal obligation that a Rapporteur Member State and co-Rapporteur Member States must be assigned to all active substances subject to renewal of approval. The Commission repeated its earlier offer to allocate the evaluation of glyphosate to a group of Member States acting jointly as rapporteurs to spread the workload, if volunteers were to come forward.

C.14 Exchange of views of the Committee on a Commission Draft Directive (EU) amending Directive 2009/128/EC to establish harmonised risk indicators.

The Commission summarised the political context and background to the development of the Harmonised Risk Indicator (HRI), explained the details of the proposed text, and presented the trends resulting from the use of the proposed HRI using the data reported to ESTAT from 2011 to date.

Twelve Member States asked for the floor. Of these, six Member States broadly supported the draft Directive as a basis for further development. No Member States fundamentally disagreed with the need for indicators and welcomed that the Commission presented a draft.

However, Member States expressed concerns related to Article 53 authorisations. Specifically, Member States identified that they do not have a legal basis to gather data on the volumes of products used under Article 53 authorisations, and that in many cases, there is a full uniform principle risk assessment supporting these authorisations, so the higher weighting is not justified.

Another concern of Member States is related to the rationale for the proposed weightings, how to interpret the results, and the possibility for the results to be misinterpreted.

The Commission invited Member States to provide comments by 10 August 2018.

M.01 1-MCP (related to point A 03)

The Commission summarised the EFSA Conclusion and highlighted that one issue could not be finalised which relates to the systematic NOAEL in toxicological studies after inhalation exposure, hence questioning the derivation of the AOEL value. However, a very low exposure of workers is expected and thus the approval of the active substance could be renewed. Member States were invited to send their comments in particular on the issue which could not be finalised in the EFSA Conclusion by 3 September 2018. A draft review report is intended to be presented at the next meeting of this Committee.

M.02 Tribenuron (related to point A 03)

Based on the amended EFSA Conclusion, the Commission will proceed with a proposal for the renewal of tribenuron. The Commission intends to proceed to a vote in the meeting of this Committee in October.

M.03 Report from the Post Approval Issue Group (PAI) meeting, including feedback from COM on maleic hydrazide (related to point A 15)

The Commission reported about the PAI meeting held on 27 and 28 June. Issues covered were active substances not supported at renewal, renewal of authorisations for products, data matching and data protection, and vertebrate studies. In addition, the European Minor Use Coordination Facility presented a draft guidance document on authorisations for minor uses. Finally the Commission confirmed that following the renewal of maleic hydrazide, Member States were competent to grant grace periods for products not in line with the conditions of renewal.

M.04 EPPO Workshop on Comparative Assessment of Plant Protection Products. (related to point A 16)

The Commission informed that EPPO is organising a Workshop on Comparative Assessment of Plant Protection Products. It will be held on 24 and 25 October 2018 in Lisbon (PT). Registration is open until 23 September 2018 via http://meeting.eppo.int/meeting.php/T5707.

M.05 Change in the DAR/RAR/Template to align with new ED criteria (related to point A 18)

The Commission informed the Committee that the adoption of the new criteria for the identification of ED properties triggered an update of the template for DAR/RAR and CLH report. This update of the template will also fix some identified typos. Member States were invited to comment by 3 September 2018.

M.06 Discussion on variants of approved active substances: request to Member States for their experience, feedback and assessment of such cases.

The Commission informed the Committee that feedback on how Member States assessed at national or zonal level new variants of approved active substances would be welcome by 3 September 2018. Such information would help to start the work on a European evaluation of variants, alongside the terms of reference earlier agreed by this Committee in January 2018.

M.07 New user interface CIRCA-BC.

Postponed.

M.08 Succinase dehydrogenase inhibitor (SDHI) fungicides.

The Commission also informed that it had been made aware about the on-going work on succinase dehydrogenase inhibitor (SDHI) fungicides in one of the Member States, the results of which will be made available to this Committee once they are available.