30 November 2016

BPC-M-17-2016

Draft minutes of the 17th meeting of the Biocidal Products Committee (BPC)

11 – 12 October 2016

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chairman of the Biocidal Products Committee (BPC) welcomed the participants to the 17th BPC meeting and informed the meeting on the changes occurred recently in the BPC membership – the appointment of a new member for Ireland and the appointment of new alternate members for Austria and Netherlands.

The Chairman informed the BPC members of the participation of 27 members, including four alternates.

Six advisers, one invited expert and one representative from accredited stakeholder organisations (ASOs) were present at the meeting. Two representatives from the European Commission also attended the meeting. Apologies were received from two ASO representatives.

Applicants were present for their specific substances and the details are provided in the summary record of the discussion for the substances and in Part III of the minutes.

2. Agreement of the agenda

The Chairman introduced the final draft agenda (BPC-A-16-2016_rev3) and mentioned the addition of one item concerning the Article 75(1)(g) request for a BPC opinion related to the comparative assessment of anticoagulant rodenticides.

To follow, the Chairman invited then any additional items. Upon proposal from BPC members two items were added: (i) update from ECHA on the developments on the criteria for endocrine disrupting properties and (ii) *in-situ* generated active substances and the role of the eCAs.

The agenda was then adopted with the proposed changes. The final version of the agenda will be uploaded to the BPC CIRCABC IG as part of the meeting minutes.

The Chairman informed the meeting participants that the meeting would be recorded for the purpose of the minutes and that the recording would be destroyed after the agreement of the minutes.

The list of meeting documents and the final version of the agenda are included in Part IV of the minutes.

3. Declarations of potential conflicts of interest to the agenda

The Chairman invited BPC members, alternates and advisers to declare any potential conflict of interest in relation to the agreed agenda. None was declared.

4. Agreement of the draft minutes and review of actions arising from BPC-16

The revised draft minutes from BPC-16 (BPC-M-16-2016 and BPC-M-16-2016_CONF), incorporating the comments received from members, were agreed.

On request of one member SECR clarified that the accordance check list will have to be submitted together with the CAR as soon as a combined check list will be available (not relevant for the running process flow).

Actions:

- **SECR:** to upload the agreed minutes from BPC-16 to the BPC CIRCABC IG and to the ECHA website after the meeting.

5. Administrative issues

5.1 Housekeeping issues

The SECR highlighted the key aspects of the housekeeping rules including the safety and security rules.

5.2 Administrative updates and report from other ECHA bodies

The Chairman introduced document BPC-17-2016-01 covering the administrative updates and the report form the other ECHA Committees, provided to members for information purposes. The Chairman noted the adoption of opinions on tetramethrin and d-*trans*-tetramethrin by the Committee for Risk Assessment and the opinion on the classification of acetaldehyde by the same committee. The Chairman mentioned that in future this document will be updated to also include the report from the PBT Expert Group and, at a later stage, from the Endocrine Disruptors Expert Group.

6. Work Programme for BPC

6.1. BPC Work Programme

The Chairman presented the revised Work Programme, mentioning that this version is a revised version of the previously disseminated one, following consultations with the MSCAs.

The Chairman noted that the current work programme version leads to 45 opinions for the Review Programme, 5 for new active substances from the BPD and 3 from the BPR. The Chairman asked the members to adhere to the planning especially for the last meeting in 2016. Members were also invited to confirm the planning for the second priority list. COM urged the eCAs to focus on the first and second priority list and mentioned that the postponing of dossiers related to the first and second priority list is an element of concern. COM also indicated that an option may be to schedule only dossiers for these priority lists in the coming years. With regard to the second priority list, the Chairman mentioned that ECHA will prepare an overview for COM indicating those dossiers that will not meet the deadline of December 2016 for the submission.

The Chairman then introduced the "Outlook" document, which gives an overall picture of all the 'streams' having an impact on the work of the BPC (Union authorisation, Article

75(1)(g) requests, Annex I inclusion, new actives under BPD, new actives under BPR, first, second and other priority lists for the Review Programme).

In view of the high workload foreseen for next year, one member suggested ECHA to consider having another BPC/WG which could focus on the product-related issues referring to a discussion at the last meeting of the Competent Authorities. In this respect the member from DK expressed concern about the availability of sufficient resources at ECHA. Another member raised the issue of the timing of the Coordination Group and Working Groups stating that their overlapping should be avoided.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) to the SECR by 21 October 2016.
- **SECR**: on the basis of the changes to update the work programme on the ECHA web site and in the BPC CIRCABC IG.

6.2 Article 75(1)(g) request comparative assessment rodenticides

The Chairman introduced the document related to the Article 75(1)(g) request from the COM concerning the comparative assessment for anticoagulant rodenticides. The BPC members were invited to agree to a derogation from the working procedure, that is appointing ECHA as rapporteur for this request. The Chairman informed the meeting that further details on the planning and steps of the process will be provided later on.

With regard to the provisional timing suggested in the document distributed for the meeting, one member expressed concerns on the late timing foreseen for the written consultation (January 2017) considering that the BPC meeting where the BPC opinion should be discussed will take place at the end of February 2017. The Chairman mentioned that the provisional timing will be further examined. Another member had comments on two elements of the draft proposal from COM, related to (i) using the risk mitigation measures report and the information received during the two public consultation to address questions on available alternatives and (ii) the proposal to omit the Tier I-B and Tier II assessment for anticoagulant rodenticides.

The Chairman concluded that the BPC agreed with the derogation from the working procedure.

Actions:

- **SECR**: to inform about the foreseen planning once the formal request from COM is received by ECHA.

7. Applications for approval of active substances

7.1 Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval

The Chairman introduced the document stating that no changes were made after the last BPC meeting.

7.2 Procedure for renaming of an active substance according to Article 13 of Regulation (EU) No 1062/2014

The procedure developed by the SECR and already discussed at the APCP Working Group was introduced by the Chairman. One member stated that the eCA and the applicant may not always agree on the renaming and therefore asked to refer to an agreement "as far as possible" in the document. Another member stated that also during the peer review process it may appear that a renaming is required and asked to reflect this in the document. The Chairman concluded that both comments will be incorporated, although renaming should normally not occur after the evaluation is submitted by the eCA to ECHA.

Actions:

- **SECR:** incorporate the comments made and make the revised document available through the BPC CIRCA BC IG.

7.3 Outcome of the e-consultation Ad-hoc Working Group on Environmental Exposure

The different questions posed in the e-consultation were discussed and concluded as follows:

1. Risk Management Measures (RMM) for PT 21

BPC was asked to clarify the correlation of the elements of condition 1a for PT 21 active substances.

Conclusion: It should be 1 and (2 or 3). For further clarification the text of the RMM could be reworded in the future as follows: „…that application, maintenance and repair activities shall (1) be conducted within a contained area to prevent losses and minimize emissions to the environment, i.e. (2) on an impermeable hard standing with bunding or (3) on soil covered with an impermeable material. Any losses or waste containing [the substance] shall be collected for reuse or disposal".

The meaning of contained area was further discussed, specifically if it includes wind protection (1b).

Conclusion: It needs to be further specified depending on the boat type and the application method: for pleasure crafts in case the antifouling is applied by brushing, wind protection is not relevant whereas for commercial ships in case the antifouling is applied by spraying, it may be relevant. This should be reflected in the PT 21 product manual currently under preparation by UK. It was further noted that wind protection should not be as such part of the standard risk mitigation measures, but if needed during product authorisation (to be followed up by the Coordination Group), it could be added as a condition for authorisation. If identified as being relevant during product authorisation, also the release pathway via air should be covered by an emission scenario to be developed (AHEE). As overall conclusion, at this point in time the standard condition currently available should not be changed.

2. RMM for PT 8

BPC was asked to clarify the intention of a specific condition on RMM for PT 8.

Conclusion: The following revised proposal for the RMM text was agreed: "... and that freshly treated timber shall be stored after treatment under shelter **or** on impermeable hard standing, or both, to prevent direct losses to soil, **sewer** or water, and that any losses of the product shall be collected for reuse or disposal".
It was further noted that there are new alternative methodologies under development (e.g. covering the ground with adsorbing materials), however for the time being these will not be reflected in the RMM.

3. Wood treated with short term antisapstain

BPC was asked if wood treated with a short term antisapstain falls under the BPR and if it would be acceptable in this case to assess only emissions during the storage period but not during service life.

Conclusion: The short term antisapstain treatment for wood during storage falls under the scope of the BPR as the BPR does not define a time limit for a biocidal efficacy. The question on if the wood is a treated article can be taken up by the Competent Authority meeting: SECR will consult with COM on this aspect. If there is proof that there is no emission to the environment, no assessment of the service life needs to be performed. It was further noted that there is the need to develop a specific emission scenario for this kind of treatments in the future.

4. Collection of tonnage data (EU/national) to determine a reference tonnage for deriving a market penetration factor

BPC was asked if the collection of tonnage data is in the remit of the BPC or if the item should be escalated to the Competent Authority meeting and if the BPC supports to start systematically the collection of tonnage data on EU/national level.

Conclusion: Collection of tonnage data (preferably via a centralised system) was as such supported by the BPC members, however since the items is not in the remit of the BPC, it should be forwarded to the Competent Authority meeting.

Actions:

- **SECR**: incorporate the comments made and make the revised document available through the BPC CIRCA BC IG.
- **SECR/(UK)**: to forward item 1b to UK (clarification on boat type/application type to be taken up by UK in the product authorisation guide for PT 21).
- **SECR**: to consult with COM if question 3 (treated article) should be forwarded to the CA meeting and to forward item 4 via COM to the Competent Authority meeting.
- **SECR**: development of an emission scenario by the Ad-hoc Working Group on Environmental Exposure for short term antisapstain treatment.

7.4 Draft BPC opinion on dichlofluanid for PT 21

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

The Rapporteur introduced the substance and the general issues related to the assessment report (AR) and opinion were then discussed in detail (modifications are described in the open issues table).

The Rapporteur clarified, upon request from a member, that the use of PPE was required because of the risks coming from the local effects of the active substance (skin sensitization and irritation properties).

The Assessment Report was agreed by the BPC, subject to the changes agreed during the meeting.

Several points were discussed on the content of the BPC Opinion. The BPC considered not relevant to include in the standard phrase on MRLs for the potential residues in fish and marine food, since the application of MRLs to fish, fish products and any other marine food products is suspended. However, in line with the opinion of tolylfluanid in PT 21, the need of an analytical method for residues in fish and seafood will be reflected in section 2.5 of the opinion.

SECR clarified that due to the change of toxicological reference values compared to the assessment of dichlofluanid in PT 8, the LoEP for PT 8 will have to be adapted.

The BPC adopted the opinion for the approval of this active substance/PT by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussion in the BPC and submit to the SECR **by 25 November 2016.**
- **SECR:** to revise the draft opinion in accordance with the discussion in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion to COM **by 4 November** 2016 and publish it on the ECHA website.

7.5 Draft BPC opinion on silicium dioxide (Kieselguhr) for PT 18

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

The rapporteur introduced the substance and the general issues related to the assessment report (AR) and to the opinion were then discussed in detail (modifications are described in the open issues table).

It was noted that the naming has to be revised throughout the opinion. The substance is listed in the Review Programme (RP) as "Silicium dioxide Kieselguhr" but it was recognised that the correct name for the substance is "Silicon dioxide Kieselguhr". In order to be more consistent, the substance will be referred to by this name and not by any other synonym, e.g. "diatomaceous earth". It was agreed that some explanation will be added at the beginning of the opinion and assessment report to explain this and to make the link to the original entry in Regulation (EU) No 1462/2014.

It will be clarified in the opinion that this is a UVCB substance, and the minimum purity of 100% will be indicated. Specific parameters for particle size distribution will be kept in the AR and in the reference specification, but will not be mentioned in the opinion as it is not necessary for the identity section for the implementing regulation. It was confirmed that this is non-confidential information.

The applicant, a member as well as SECR raised the issue that different AEC values seem to appear in the revised AR than the ones agreed during the WG Human Health ad hoc follow up. Even though the argumentation of the Rapporteur was considered logical (using TWA approach and extrapolate the values to 8h interval) for deriving the AEC values, it was not agreed during the ad hoc follow up discussions. The Rapporteur stressed that they do agree with the conclusion of the ad hoc follow up, but would like to report the TWA adjusted values as well. The Chairman concluded that the SECR will clarify with the Rapporteur how to report the AEC values in the AR and List of Endpoints.

Some members noted that there is a discrepancy for the AEC values with national levels for workplace exposure and asked how to inform at EU level the relevant regulatory bodies. The Rapporteur didn't know how to inform other regulatory bodies either and the SECR proposed to park this point.

The BPC adopted by consensus the opinion for the approval of this active substance/PT combination.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussion in the BPC and submit to the SECR **by 25 November 2016.**
- **SECR:** to revise the draft opinion in accordance with the discussion in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion to COM **by 4 November** 2016 and publish it on the ECHA website.

7.6 Draft BPC opinion on silicon dioxide (as a nanomaterial formed by aggregates and agglomerates)(Degussa/Evonik)

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

The substance was renamed into "pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated". The reason for renaming will be explained in the CAR, AR and opinion to make the link between the original and the new name. SECR will clarify with COM whether an invitation to take over the role of participant following this redefinition is needed according to Article 14(1)(b) of Regulation (EU) No 1462/2014 (for the substance that is covered by the original entity but not covered by the new one).

With regard to the specification, the same level of information as was reported in the implementing regulation for the already approved silicon dioxide will be reported. The reference specification will include the following characteristics: minimum purity, carbon content, primary particle size, specific surface area and the size of stable aggregated

particles and the shape of the particle (as these are reference structural characteristic and related to the specific surface treatment). The opinion and consequently, the implementing regulation will not include the shape of the particle in order to be consistent with the approved nano silicon dioxide. One member commented that they would not agree on including the aggregated particle size as a parameter in the reference specification as it was concluded by the APCP WG not to include it.

A member expressed objection to the human health assessment due to inhalation toxicity. The member did not agree that a read across study with a completely different surface coating can be used for setting a reference value. Basis requirements set in the ECHA Read-Across Assessment Framework were not met. The same objection had been expressed and noted during the TOX WG ad hoc follow up. This opinion was then not supported by the other ad hoc follow up group members (as the study was considered relevant, valid and reliable). At the BPC meeting, hearing the objections of the member, another member supported this opinion.

The BPC adopted by majority the opinion for the approval of this active substance/PT combination. The member who did not support the approval will send their minority position within 7 days.

Actions:

- **Rapporteur**: to revise the assessment report in accordance with the discussion in the BPC and submit to the SECR **by 25 November 2016**.
- **Member**: to submit to SECR the minority position by October 21.
- **SECR**: to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR**: to consider if an invitation to take over the role of the participant according to Article 14 of Regulation (EU) No 528/2012 needs to be published.
- **SECR**: to forward the adopted opinion to COM **by 4 November 2016** and publish it on the ECHA website.

7.7 Draft BPC opinion on PHMB (1600; 1.8) for PT 5

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

The Rapporteur introduced the substance and the general issues related to the assessment report (AR) and opinion were then discussed in detail.

The Assessment Report was agreed by the BPC, subject to the changes agreed during the meeting.

The Rapporteur explained that only a limited use can be considered acceptable, provided the manure/slurry is disposed on arable land only. Following consultation at national level it was concluded that the risk mitigation measure to ensure the manure is not disposed on agricultural land is not feasible. The manure is collected from various sources, left to dry and usually gets mixed. The origin of the manure at this stage is difficult to determine

and labelling is not a feasible option. If PHMB (1600; 1.8) containing manure has to be treated differently, a monitoring plan and additional analytical measurements for PHMB (1600; 1.8) would be required for the quality control of the manure. This would increase the costs of control. The BPC members were supporting that the risks cannot be mitigated and therefore PHMB (1600; 1.8) for PT 5 should not be approved.

The SECR noted that the revised scenario for PT 18, where 10 applications on agricultural land was considered instead of 1, was applied for the first time. As the substance has a high DT50 and readily adsorbs to soil, with only 1 application the outcome may have been different. However, the revision was considered necessary, as the new guidance was correcting major mistakes of former guidance and was considered more reliable than the former one. This is in line with the BPC document "Applicability time of new guidance and guidance-related documents in active substance approval". In addition, the release of the active substance to manure was underestimated. The use of a lower in-use concentration for water disinfection was not investigated, neither by the Environment WG nor by the Efficacy WG.

The member from DK expressed concern over the legal basis for using this revised guidance for the evaluation of an active substance submitted before 1 September 2013 referring to Article 90 of the BPR. COM referring to the "Note on the principles for taking decisions on the approval of active substances under the BPR" stated that the main consequence here relates to substances meeting the exclusion and substitution criteria in terms of approval period. With respect to the application of new guidance, as guidance is continuously evolving, therefore if the new guidance is more appropriate it may be used.

The presentation of dietary risk assessments in the CAR and AR was discussed in general. It was agreed that if such an assessment has been performed, it should be included in an annex to the CAR. The outcome will be described in the opinion, provided it is clearly stated that it is a preliminary assessment based on draft guidance subject to change. The assessment may need to be finalised at product authorisation level. Some members pointed out that the preliminary assessment should not have an implication on the provisions under section 2.3 of the opinion, but may be highlighted under section 2.4 as an element for product authorisation.

Several members raised concerns that in the absence of guidance these issues are postponed to product authorisation resulting in considerable delays in the process. SECR acknowledged the burden for product authorisation and considered related guidance development as high priority, and emphasised the need to finalise the CA document that provides the basic principles for this guidance.

With respect to the assessment of animal safety, an urgent need to develop guidance was highlighted. A member considered that the information available would have been enough to conclude on the risks had it been for approval, thereby preventing to postpone such a critical issue to product authorisation. In their opinion, for such a use, animal safety is a crucial part of an approval and is required by Article 19(1)(b)(iii) of the BPR. The SECR explained that in the case of this active substance the preliminary assessment was performed based on suggestions made at the WG Human Health. However, the eCA proposal was not peer-reviewed. The issue has been raised repeatedly lately at this working group. To be able to develop guidance, protection goals need to be set by the Competent Authority meeting. The SECR will initiate guidance development. One member

highlighted the urgency of developing this guidance document taking into account the running union authorisation applications for PT 3 where this will also be an issue. On request of another member SECR clarified that as soon as this new guidance is available, it will have to be used for product authorisation immediately. In general, if such an element is included in the BPC opinion because of lacking guidance, this is independent from the 2 years deadline outlined in CA-July12-Doc.6.2.d - Relevance of new guidance.

The BPC adopted by consensus the opinion for the non-approval of this active substance/PT combination.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussion in the BPC and submit to the SECR **by 25 November 2016.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion to COM **by 4 November 2016** and publish it on the ECHA website.
- **SECR:** to initiate guidance development on animal safety.

7.8 Working procedure for Union Authorisation

The working procedure for Union Authorisation was agreed by the BPC with minor changes:

- Section 4.1 "Submitting PARs and draft SPCs": further clarification will be added about the format in which the draft SPC is submitted. In addition, it will be explained that an early WG discussion should be normally foreseen for each UA application, prior to the end of the eCA evaluation, but the eCA will have the possibility to opt out for the early WG discussion, if the discussion is considered not necessary.
- Table 1 "Description of the steps in the peer review process of Union authorisation applications": during the meeting it was proposed to exchange the time limit of steps 5 and 6 (commenting phase and trilateral discussions and response to comments table, respectively) to give Member States Competent Authorities more time to reply to the comments received. Nonetheless, it was agreed to maintain the time limits as provided in the document and to revise the working procedure in light of experience. Moreover, it was noted that for the peer-review process, the use of CIRCABC as the communication platform would allow more flexibility with regard to the distribution of documents and commenting. SECR agreed to include CIRCABC, where relevant.
- Timelines: the timelines were agreed and Option 2 was the preferred approach for process flow 18.

Actions:

- **SECR:** to revise the working procedure for Union authorisation and the timelines in accordance with the discussions in the BPC and to publish them on the BPC webpage in the ECHA website.

7.9 Additional data submitted after active substance approval:

a. 1R-trans-phenothrin

The member of Ireland presented the additional data submitted after the approval of this active substance and the results of the BPC consultation. The revised LoEP was agreed by the BPC.

b. copper, granulated

The member of France presented the additional data submitted after the approval of this active substance and the results of the BPC consultation. The revised LoEP was agreed by the BPC.

Actions:

- **SECR:** disseminate the Assessment Report including the revised LoEP on S-CIRCABC and on the ECHA website.

8. Any other business

a. Consultation BPC on ECHA report on the regulatory applicability of alternative and non-animal approaches (3R's)

ECHA informed the BPC on this ongoing project. A consultation of the BPC as well as RAC and MSC on the draft report is planned for November – December 2016.

Actions:

- **SECR:** to launch consultation planned for November – December.

b. Update on the developments on criteria for endocrine-disrupting properties

ECHA presented an update on the most recent developments focussed on the preparation of guidance.

c. In-situ generated active substances and the role of the eCAs

The Chairman referred to three aspects: i) applications received by ECHA related to the Article 93 dead-line of 1 September 2016; ii) compliant notifications received by ECHA related to the Article 13 dead-line of 27 April 2016; iii) on-going evaluations under the Review Programme. An overview of all applications and compliant notifications will be prepared by ECHA. Subsequently, ECHA will initiate some coordinating activities relating to time lines and situations where potentially different eCAs are involved. COM informed that for the submissions following a compliant notification under Article 13, the eCA is already determined as these in-situ generated active substances were already included in the Review Programme. This was disputed by some members. The Chairman concluded this will need to be discussed at the Competent Authorities meeting. For the submission related to Article 93 (and 94) COM informed that here the applicant can choose the eCA. However,

the preference is to refer all applications for the same in-situ generated active substance to the same eCA for efficiency reasons.

9. Agreement of the action points and conclusions

Part II contains the main conclusions and action points which were agreed at the meeting.

Part II - Main conclusions and action points

Agreed at the 17th meeting of BPC

11-12 October 2016

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
Item 2 - Agreement of the agenda	
The final draft agenda was agreed with the inclusion of two additional AOB items.	**SECR:** to upload the agreed final agenda to the BPC CIRCABC IG as part of the draft meeting minutes after the meeting.
Item 4 - Agreement of the minutes and review of actions from BPC-16	
The revised version of the minutes of BPC-16 was agreed as proposed subject to several editorial modifications.	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website after the meeting.
Item 5 – Administrative issues	
5.2 Administrative issues	
-	
Item 6 - Work programme for BPC	
6.1. Revised Work Programme 2016-2017 and Outlook for BPC	
	Members: to send information on any further changes to the Work Programme (WP) in particular on the second priority list, to the SECR by **21 October 2016**. **SECR:** on the basis of the changes to update the WP on the ECHA web site and in the BPC CIRCABC IG.
6.2. Article 75(1)(g) request comparative assessment rodenticides	
It was agreed that ECHA will act as a rapporteur for this request deviating from the framework for Article 75(1)(g) requests.	**SECR:** inform about the foreseen planning once the request is received by ECHA.
Item 7 - Applications for approval of active substances	
7.1.a) Catalogue of specific conditions and elements to be taken into account at the product authorisation stage	
-	

7.2 Procedure for renaming of an active substance according to Article 13 of Regulation (EU) No 1062/2014	
The procedure proposed by the SECR was agreed by the meeting subject to some minor modifications.	**SECR:** incorporate the comments made and make the revised document available through the BPC CIRCA BC IG.
7.3 Outcome of the e-consultation Ad-hoc Working Group on Environmental Exposure	
The different questions posed in the e-consultation were discussed and concluded.	**SECR:** incorporate the comments made and make the revised document available through the BPC CIRCA BC IG.
7.4 Draft BPC opinion on dichlofluanid for PT 21	
The BPC adopted by consensus the opinions for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 25 November 2016.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion to COM **by 4 November 2016** and publish it on the ECHA website.
7.5 Draft BPC opinion on silicium dioxide (Kieselguhr) for PT 18	
The BPC adopted by consensus the opinion for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussion in the BPC and submit to the SECR **by 25 November 2016.** **SECR:** to revise the draft opinion in accordance with the discussion in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion to COM **by 4 November 2016** and publish it on the ECHA website.
7.6 Draft BPC opinion on silicon dioxide (as a nanomaterial formed by aggregates and agglomerates) (Degussa/Evonik) for PT 18	
The BPC adopted by majority the opinion for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussion in the BPC and submit to the SECR **by 25 November 2016.** **Member**: to submit to SECR the minority position by October 21. **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR**: to consider if an invitation to take over the role of the participant according to Article 14 of Regulation (EU) No 1062/2014 needs to be published.

	SECR: to forward the adopted opinion to COM **by 4 November 2016** and publish it on the ECHA website.
7.7 Draft BPC opinion on PHMB (1660; 1.8) for PT 5	
The BPC adopted by consensus the opinion for non-approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussion in the BPC and submit to the SECR **by 25 November 2016.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion to COM **by 4 November 2016** and publish it on the ECHA website. **SECR:** to initiate guidance development on animal safety.
7.8 Working procedure for Union Authorisation	
The revised Working procedure was agreed.	**SECR:** incorporate the comments made and make the revised document available through the BPC CIRCA BC IG and the ECHA website.
7.9 Revised Assessment Reports following the submission of data after active substance approval: a) 1R-trans-phenothrin; b) copper, granulated	
Meeting agreed to the revised LoEP for both active substances.	**SECR:** to disseminate the Assessment Report including the revised LoEP on S-CIRCABC and on the ECHA website.
Item 8 - AOB	
8.1 Consultation BPC on ECHA report on the regulatory applicability of alternative and non-animal approaches (3R's)	
ECHA informed on the ongoing project related to 3R's	**SECR:** to launch consultation planned for November – December.
8.2 In-situ generated active substances and the role of the eCAs	
8.3 Update on ED activities	
The SECR informed the BPC on the ongoing ED activities.	

Part III - List of Attendees

Members	European Commission
BORGES Teresa (PT)	CHATELIN Ludovic (DG SANTE)
BROVKINA Julija (LV)	KUSENDILA Christophe (DG SANTE)
BROWN Finbar (IE)	
CABALLO DIÉGUEZ Covadonga (ES)	**Advisers**
ČEBAŠEK Petra (SI)	BOITIER Caroline (FR)
CHÉZEAU Aurélie (FR)	CROIZE-POURCELET Gilles (FR)
COSTIGAN Michael (UK)	MEDJO BYABOT Corettie (FR)
DRAGOIU Mihaela-Simona (RO)	PALOMÄKI Jaana (FI)
GIORDMAINA Wayne (MT)	PÜRGY Reinhild (AT)
GORDON Suzanne Collett (NO)	RITZ Vera (DE)
HAHLBECK Edda (SE)	
JÄGER Stefanie (DE)	**Accredited Stakeholder Organisations**
JOHN Nina (AT)	MONTMOREAU Bertrand (CEPA)
KOIVISTO Sanna (FI)	
KOMEN Corine (NL)	**ECHA Staff**
LARSEN Jørgen (DK)	ANTAL Diana
MERISTE Anu (EE)	ESTEVAN MARTINEZ Carmen
MIKOLASKOVA Denisa (SK)	JANOSSY Judit
SZÁNTÓ Emese	LOPEZ SERRANO Paloma
VAN BERLO Boris (BE)	NEGULICI Ligia
VRHOVAC FILIPOVIC Ivana (HR)	PECORINI Chiara
ZIGRAND Jeff (LU)	SCHIMMELPFENNIG Heike
ZOUNOS Athanasios (EL)	VAN DE PLASSCHE Erik
Alternate members	
CRESTI Raffaella (IT)	
GAVRIEL Alexandros (CY)	
MIKOLAS Jan (CZ)	
PYTHON François (CH)	
Invited expert	
HUSZAL Sylwester (PL)	

Applicants	Apologies
ARNOLD Matthias (LANXESS) for dichlofluanid PT 21	CAZELLE Elodie (AISE)
DIETZ Carolin (Biofa AG) for silicium dioxide PT 18	MIHAI Camelia (CEFIC)
DIN Salahud (LONZA) for PHMB PT 5	REID Kirsty (Eurogroup for Animals)
MEIER Monika (Evonik GmbH) for silicon dioxide (as a nanomaterial formed by aggregates and agglomerates) PT 18	
Experts accompanying applicants	
WERNER Michael, accompanying DIETZ Carolin, for silicium dioxide PT 18	

Part IV - List of Annexes

Annex I List of documents submitted to the members of the Biocidal Products Committee

Annex II Final agenda of BPC-17

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-17 meeting

Meeting documents				
Agenda Point	**Number**	**Title**		
2	BPC-A-17-2016_rev3	Draft agenda		
4	BPC-M-16-2016 BPC-M-16-2016_CONF	Draft minutes from BPC-16		
5.2	BPC-17-2016-01	Administrative issues and report from the other Committees		
6.1	BPC-17-2016-02 BPC-17-2016-03	BPC updated Work Programme 2016-2017 Outlook BPC		
6.2	BPC-17-2016-14a	Article 75(1)(g) request comparative assessment rodenticides		
7.2	BPC-17-2016-05a BPC-17-2016-05_annex	Procedure for renaming of an active substance according to Article 13 of Regulation (EU) No 1062/2014		
7.3	BPC-17-2016-06	Outcome of the e-consultation Ad-hoc Working Group on Environmental Exposure		
7.8	BPC-17-2016-12a BPC-17-2016-12b	Working procedure for Union Authorisation Timelines peer review Union Authorisation		
7.9	BPC-17-2016-13a BPC-17-2016-13b BPC-17-2016-13c	Additional data submitted after active substance approval for a) 1R-trans-phenothrin b) Copper, granulated		
Substance documents				
Agenda Point	**Number**	**Substance-PT**	**eCA**	**Title**
7.4	BPC-17-2016-11A	Dichlofluanid PT 21	UK	Draft BPC opinion
	BPC-17-2016-11B			Assessment report
	BPC-17-2016-11C			Open issues
7.5	BPC-17-2016-08A	Silicium dioxide (Kieselguhr) PT 18	FR	Draft BPC opinion
	BPC-17-2016-08B			Assessment report
	BPC-17-2016-08C			Open issues
7.6	BPC-17-2016-09A		FR	Draft BPC opinion

	BPC-17-2016-09B	Silicon dioxide (as a nanomaterial formed by aggregates and agglomerates) (Degussa/Evonik) PT 18		Assessment report
	BPC-17-2016-09C			Open issues
7.7	BPC-17-2016-10A	PHMB (1600; 1.8) PT 5	FR	Draft BPC opinion
	BPC-17-2016-10B			Assessment report
	BPC-17-2016-10C			Open issues

06 October 2016
BPC-A-17-2016_rev3

Final agenda

17th meeting of the Biocidal Products Committee (BPC)

11-12 October 2016

ECHA Conference Centre, Annankatu 18, Helsinki

Starts on 11 October at 09:30, ends on 12 October at 13:00

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-17-2016-rev2
For agreement

3. – Declarations of potential conflicts of interest to agenda items

4. – Agreement of the minutes and review of actions from BPC-16

BPC-M-16-2015
For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

BPC-17-2016-01
For information

6. – Work programme for BPC

6.1. BPC Work Programme

BPC-17-2016-02 and BPC-17-2016-03
For information

6.2. Article 75(1)(g) request comparative assessment rodenticides

BPC-17-2016-14a and 14b
For agreement

7. – Applications for approval of active substances*

7.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval

For information

7.2. Procedure for renaming of an active substance according to Article 13 of Regulation (EU) No 1062/2014

BPC-17-2016-05a and 5b

For agreement

7.3. Outcome of the e-consultation Ad-hoc Working Group on Environmental Exposure

BPC-17-2016-06

For agreement

7.4. Draft BPC opinion on dichlofluanid for PT 21

Previous discussion(s): WG-III-2016

BPC-17-2016-11A, B and C

For adoption

7.5. Draft BPC opinion on silicium dioxide (Kieselguhr) for PT 18

Previous discussion(s): WG-III-2016

BPC-17-2016-08A, B and C

For adoption

7.6. Draft BPC opinion on silicon dioxide (as a nanomaterial formed by aggregates and agglomerates) (Degussa/Evonik) for PT 18

Previous discussion(s): WG-III-2016

BPC-17-2016-09A, B and C

For adoption

* For the discussions of the draft BPC opinions at least the following documents will be distributed: a draft BPC opinion (denoted by A), a draft assessment report which may cover more than one PT (denoted by B) and a document containing open issues covering all the PTs to be discussed for that substance (denoted by C).

7.7. Draft BPC opinion on PHMB (1660; 1.8) for PT 5

Previous discussion(s): WG-III-2016

BPC-17-2016-10A, B and C

For adoption

7.8. Working procedure for Union Authorisation

BPC-17-2016-12a and 12b

For agreement

7.9. Additional data submitted after active substance approval:

a. 1R-trans-phenothrin

BPC-17-2016-13a, 13b, 13c and 13d

For information

b. copper, granulated

For information

Item 8 – Any other business

a. Consultation BPC on ECHA report on the regulatory applicability of alternative and non-animal approaches (3R's)

b. Update on Endocrine Disruptors activities

c. In-situ generated active substances and the role of the eCAs

Item 9 – Agreement of the action points and conclusions

For agreement

Provisional timeline for the

17th meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Annankatu 18, Helsinki

11 October 2016: starts at 09:30; 12 October 2016: ends at 13:00

Please note that the timings indicated below are provisional and subject to possible change. They are distributed to participants on a preliminary basis.

Tuesday 11 October: morning session

Items 1-5	Opening items and administrative issues
Item 6	Work programme for BPC 2016-2017
Item 7.1	Catalogue of specific conditions and elements to be taken into account at the product authorisation stage
Item 7.2	Procedure for renaming of an active substance according to Article 13 of Regulation (EU) No 1062/2014
Item 7.3	Outcome of the e-consultation Ad-hoc Working Group on Environmental Exposure
Item 7.4	Draft BPC opinion on dichlofluanid for PT 21

Tuesday 11 October: afternoon session

Item 7.5	Draft BPC opinion on silicium dioxide for PT 18
Item 7.6	Draft BPC opinion on silicon dioxide (as a nanomaterial formed by aggregates and agglomerates) for PT 18

Wednesday 12 October: morning session

Item 7.7	Draft BPC opinion on PHMB for PT 5
Item 7.8	Working procedure for Union Authorisation
Item 7.9	Additional data submitted after active substance approval for:
	a) 1R-trans-phenothrin
	b) copper, granulated
Item 8	AOB
Item 9	Agreement of the action points and conclusions

End of meeting

o0o