23 December 2015

BPC-M-13-2015

Minutes of the 13th meeting of the Biocidal Products Committee (BPC)

8 – 11 December 2015

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chairman of the Biocidal Products Committee (BPC) welcomed the participants to the BPC meeting and mentioned this was the first meeting in which the Luxembourgish alternate member, Svenja Ensch, participated.

The Chairman informed the BPC members of the participation of 26 members, including four alternates.

Thirteen advisers, one invited expert, two representatives of the European Commission and two representatives from accredited stakeholder organisations (ASOs) were present at the meeting. Apologies were received from two members and one ASO representative.

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-13-2015_rev1) and indicated that the following documents could not be prepared in time by the SECR for this meeting and will be on the agenda of the next meeting:

- Proposal to amend the working procedure for the active substance approval process based on the workshop;
- Formats for the Assessment Report and opinion for active substance approval;
- Disseminating the revised Assessment Report following the submission of new data after active substance approval;
- Catalogue of specific conditions and elements to be taken into account for product authorisation. This document was not prepared due to the on-going discussions on the "new wording for active substance approval".

The Chairman then informed the meeting that formaldehyde for PT 2 was removed from the agenda.

To follow, the Chairman invited then any additional items. Three items were added, upon proposal from BPC members: (i) update on harmonising the dossier format between biocides and harmonised classification and labelling under CLP and (ii) update on guidance development related to in-situ generated active substances, and (iii) information on a work sharing proposal of SECR presented at Human Health and Environment working groups meetings.

The agenda was 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-12

The revised draft minutes from BPC-12 (BPC-M-12-2015), incorporating the comments received from members, were agreed.

Under the follow-up of the actions arising from BPC-12, it was communicated to BPC members that with regard to the renewal of anticoagulant active substances, a consultation between ECHA, COM and the involved eCAs was organised by ECHA on 5 November and further coordination meetings will be arranged by ECHA. ECHA is also initiating the public consultation. The topic is scheduled for discussion in the first meetings of 2016 of the Environment Working Group (on PBT assessment due to the submission of new data) and in the Efficacy Working Group focussing on resistance. All renewals are regarded as "limited" evaluations (so not full under Article 15) leading to 180 days for the evaluation and 90 days for the BPC opinion. This means the Assessment Reports will have to be submitted to ECHA by the end of March 2016 and the draft opinions are scheduled for the June 2016 meeting.

The Chairman also provided updates concerning the disinfectants project. He mentioned that a kick-off meeting with the contractor will still be organised in December 2015. The Chairman then presented the scope of the project, which comprises four work packages: (i) preparation of instructions for the evaluation of disinfectants; (ii) preparation of assessment and evaluation guidelines for efficacy of drinking water disinfectants (PT 5); (iii) coordination of evaluating Competent Authorities, where four workshops are foreseen and (iv) providing support to individual Member States.

The Chairman then communicated that new meeting dates will be scheduled in January and that the table with the "Timelines for the peer review of active substance evaluations" will then be modified introducing new process flows. These process flows will indicate the submission windows for the eCA to submit their evaluation to ECHA for the accordance check.

Actions:

- **SECR:** to upload the agreed minutes from BPC-12 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-13-2015-01 covering the administrative updates and the report from the other ECHA Committees, provided to members for information purposes. The Chairman reported that the migration of the BPC interest group from CIRCABC to Secure-CIRCABC was successful and he also informed the participants about the migration of the Review Programme applications to R4BP 3 at the beginning of 2016, in view of which the working procedure was amended. The discussion on the amendment of the work procedure continued under item 5.3.

The participants were them informed that two new organisations were accepted by ECHA as accredited stakeholder observer with an interest in the biocides field: ECFF - European Chilled Food Federation - and CEPA - Confederation of European Pest Management Associations. Following the agreement of the BPC to accept these organisations as accredited stakeholders, the list of accredited stakeholders published on the ECHA website will be updated.

Actions:

- **SECR:** to update the accredited stakeholders list on the ECHA website.

5.3 Updated BPC Working Procedure

The Chairman introduced the updated working procedure and mentioned that the update reflects the future use of R4BP 3 for formal communications and exchange of documents of SECR with the applicants, eCAs and COM, following the migration of the Review programme applications to R4BP 3. In practice, this means that the SECR will take over some of the tasks which were up to now carried out by the eCA, for example sending the Assessment Reports to the applicant for the BPC meetings. Submissions of the Assessment Reports or the draft opinion will continue to take place via CIRCABC. In the revised working procedure it is indicated in each step via which tool (R4BP, CIRCABC or a ECHA functional mailbox) the communication is foreseen to take place. The Chairman explained that, as this is regarded by the SECR as more an administrative change of the working procedure, the BPC is asked to agree on this revision. It was also communicated that at the beginning of 2016 MSCAs, accredited stakeholder observers and applicants will be informed about this change through different communication channels: update of R4BP manuals and dedicated communication via e-news etc.

Several members indicated that the communication tools within the R4BP should be further improved if all communications have to be made via the R4BP, as it was requested in November in the R4BP IT user group. ECHA SECR noted this request.

Actions:

- **SECR:** to upload the revised version of the Working Procedure to the ECHA website.

- **SECR:** to consider how the communication function of R4BP 3 can be improved.

6. Work Programme for BPC for 2015– 2016

6.1. Revised Work Programme 2015-2016, Outlook and other related items

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 if all opinions are adopted at the current meeting the total number will be 50 of which 47 Review Programme existing active substances and 3 new actives (including lactic acid). For 2016 in total 87 opinions are currently scheduled: 24 opinions for the first priority list; 16 opinions for the second priority list; 26 opinions for the other priority lists; 13 opinions for new active substances (BPD or BPR) and 8 opinions on renewal of rodenticides.

For the second priority list (PT 3, 4 and 5) still 95 opinions have to be delivered by the end of 2017.

The Chairman asked members to stick to the work programme, especially for the first priority lists. With respect to the forecast of resources for MSCAs as well as the SECR and for the predictability for applicants for product authorisation this is crucial.

The Chairman gave a short presentation which included an update on rodenticide renewals, on the disinfectant project and backlog dossiers. The presentation was distributed via the CIRCABC IG after the meeting.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) to the SECR by 18 December 2015.
- **SECR**: on the basis of the changes to update the WP on the ECHA web site and in the BPC CIRCABC IG.
- **SECR**: to contact eCAs to have an overview on the status of the second priority list substances.

7. Applications for approval of active substances

7.2 Draft BPC opinion on Bardap 26 for PT 8

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 discussion on the draft opinion followed a commenting round concerning sections 2.3, 2.4 and 2.5 launched after BPC-12. The Chairman noted that the assessment report (AR) was already agreed in the previous BPC meeting.

The provision on risk mitigation measures related to the storage and the application phase of wood preservatives has been applied to all PT 8 substances. It was considered as a means to promote good practices for the use of wood preservative biocidal products. A member noted that moving the provision to the elements to be taken into account during product authorisation, would result in a change in this practice as this risk mitigation would no longer be a part of the legal text in the implementing regulation. Following the discussion, the BPC agreed to keep this general provision in section 2.3.

A further agreement was to remove the word "possible" where risks were identified for the representative product as the intention was only to flag that with the information available and the risk mitigation measures assessed a risk was identified. However, the risk assessment can be refined at product authorisation.

It was agreed that where an unacceptable risk is identified and no risk mitigation measure(s) is proposed, the element should be worded to indicate that if the risk remains (following evaluation at product authorisation), products for that use cannot be authorised. It was noted that further information or other risk mitigation measures may be available at product authorisation. A harmonised wording will be developed and included by the SECR in the opinions, where relevant.

A discussion took place whether the efficiency and effectiveness of the risk mitigation measures proposed need to be demonstrated at product authorisation. A member commented that for PT 8, for the general provision related to storage and the application phase it should not be required as with the applied RMM, exposure of the specific environmental compartments can be excluded. This is in contrast to other types of RMM applied e.g. for on-site pre-treatment where exposure is assumed to be reduced, but cannot be excluded. Another member disagreed that even for a specific use local discharge to a stream cannot be excluded; release to the environment is monitored and monitoring may be part of an integrated pollution prevention licence. However, the member agreed that for consistency with earlier PT 8 approvals it can be argued that demonstration of efficiency and effectiveness should not be required.

The BPC adopted the opinion by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 21 January 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 January 2016 and publish it on the ECHA website.

7.3 Draft BPC opinion on DBDCB for PT 6

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 discussion on the draft opinion followed a commenting round concerning sections 2.3, 2.4 and 2.5 launched after BPC-12. The Chairman noted that the AR was already agreed in the previous BPC meeting.

A member commented that the issue of the derivation of the long-term Acceptable

Exposure Level (AEL) discussed at BPC-12 was not resolved. However, it was maintained to proceed as agreed earlier: the AR was agreed at BPC-12 (safe uses were identified using this AEL) with the AEL used in the draft CAR. After the adoption of the opinion the BPC Human Health WG will discuss this reference value and the list of endpoints (LoEP) may be amended. Thereafter, the BPC will have to agree on the AR containing the amended LoEP. The applicant noted that other PT applications for DBDCB are in the pipeline.

The BPC adopted the opinion by consensus; one member abstained disagreeing with the procedure for the revision of the AEL.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 12 February 2016.
- **Rapporteur:** to send to SECR a document on the derivation of AELs for discussion at the first WG Human Health of 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 January 2016 and publish it on the ECHA website.

7.4 Draft BPC opinion on Ampholyt 20 for PT 2 and 4

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 discussion on the draft opinion followed a commenting round concerning sections 2.3, 2.4 and 2.5 launched after BPC-12. The Chairman noted that the AR was already agreed in the previous BPC meeting.

The discussion focused mainly on the need for information on the efficacy of the proposed risk mitigation measures to reduce exposure of the environment. It was acknowledged that environmental risks from the use assessed were low and if pre-treatment and/or dry cleaning are considered, this most likely will lead to acceptable levels of exposure. However, if risks would be higher, the ability of the RMM to reduce the risk to an acceptable level will, at the end, depend on the actual height of the risk. The supporting information on the efficacy of the measures are only required if the measures are applied. It was noted that the supporting information requirement might be applicable for disinfectants in general, as high quantities are used for hygiene purposes that are discharged to the environment under local conditions. A member commented that it was especially important for this substance as the impact of the proposed measures on reducing the risks is unknown.

The BPC adopted the opinions on ampholyt PT 2 and PT 4 by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 21 January 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 January 2016 and publish it on the ECHA website.

7.5 Draft BPC opinion on biphenyl-2-ol for PT 3

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

The Chairman clarified that biphenyl-2-ol for PT3 could not be approved at BPC-11 due to issues regarding the environmental risk assessment calculations.

To the AR there was only one editorial comment. In regards to the Opinion several comments were discussed, to which the eCA agreed. There were some minor comments around the wording of the opinion in section 2.4 "elements to be taken into account when authorising products" and section 2.3 "BPC opinion on the application for approval of the active substance".

BPC agreed to add to the opinion in section 2.3 a reference to the possibility for Annex I inclusion of the BPR. The overall conclusion combining environment and human health is missing and was agreed to be added.

The opinion was adopted by consensus by the BPC.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 21 January 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 January 2016 and publish it on the ECHA website.

7.6 - 7.8 Draft BPC opinions on copper thiocyanate for PT 21, coated copper flake for PT 21 and cuprous oxide for PT 21

The Chairman welcomed the applicant for these items. 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 pointed out that, in agreement with COM and ECHA, the opinions were not drafted according to the recently agreed wording for the conditions but following the general line for the generic conditions as already agreed for antifouling substances.

General issues common to all the ARs and opinions for the PT 21 copper substances were first discussed. It was agreed that the classification should be harmonised with the

RAC opinions (where M-factors are proposed) and that adequate reference to the ATP proposals should be added.

The rapporteur proposed that a new study on dermal adsorption should be required at product authorisation stage. However, the majority of the members considered that a new study according to current guidance would not give reliable results and that further studies should not be required until new guidance becomes available. It was also mentioned that new guidance will most likely not be available in time for product authorisation. It was therefore concluded that a workshop needs to be organised in the beginning of next year in order to discuss how to conduct tests on dermal adsorption for PT 21 paints and how to harmonise the assessments of these biocidal products.

It was also suggested that a general discussion on MAMPEC interpretation at WG level is required in order to harmonise assessments for product authorisation.

The members agreed that an assessment of the substitution criteria B and T should be added even though the P-criterion does not apply for inorganic substances.

The issues related to the AR and opinion for each active substance were then discussed in detail:

Copper thiocyanate

It was agreed that further hazard information on thiocyanate should be required at product authorisation stage if a refinement of the assessment is needed.

The AR was agreed by the BPC, subject to the changes agreed during the meeting. The opinion was adopted by consensus. The member from DK abstained due to disagreement with the use of an assessment factor of 1 used for the derivation of some PNEC values. The members from SE and NO expressed their disagreement with the use of the assessment factor of 1.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 21 January 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 January 2016 and publish it on the ECHA website.
- **SECR:** to initiate workshop on performing and assessing dermal absorption studies for antifouling paints.

Cuprous oxide

All three sources were accepted as reference sources and maximum levels of impurities were agreed. It was concluded that there is a need for a further general discussion when a technical equivalence assessment is required for sources not meeting the reference specification but meeting the maximum levels set for the approval.

It was also concluded that the CLP regulation drives the classification for the active substance but that for some specific sources a classification as skin sensitizer category 1 is required due to the level of nickel as impurity, assuming that the nickel is in a soluble form. Further information could be submitted at product authorization stage on the actual form of nickel present in the specific source.

The AR was agreed by the BPC, subject to the changes agreed during the meeting. The opinion was adopted by consensus. The member from DK abstained due to disagreement with the use of an assessment factor of 1 used for the derivation of some PNEC values. The members from SE and NO expressed their disagreement with the use of the assessment factor of 1.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 21 January 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 January 2016 and publish it on the ECHA website.
- **SECR:** to clarify if technical equivalence assessment is required when the impurity level is lower than the maximum content specified in the reference specification but higher than the content set in the specification for the reference source.

Copper flake, (coated with aliphatic acid)

The naming of the active substance was discussed. One member was of the opinion that the name should be "copper" in line with the agreement at the APCP Working Group, and pointed out that neither shape nor impurity should affect the naming. However, the majority of the members agreed to use the name copper flake (coated with aliphatic acid) in order to harmonise with the CLP process.

The AR was agreed by the BPC, subject to the changes agreed during the meeting. The opinion was adopted by consensus. The member from DK abstained due to disagreement with the use of an assessment factor of 1 used for the derivation of some PNEC values. The members from SE and NO expressed their disagreement with the use of the assessment factor of 1.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 21 January 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 January 2016 and publish it on the ECHA website.

7.9 Draft BPC opinion on granulated copper for PT 8

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 naming of the active substance was discussed and the rapporteur pointed out that new data were provided by the applicant after the APCP Working Group. The new data were sent for an e-consultation before the BPC with the proposal to name the substance as granulated copper. The majority of the members agreed to use the name copper, granulated in order to harmonise with the CLH process. One member disagreed and stated that in their opinion the active substance is neither copper nor granulated copper but a copper complex, and no proper risk assessment has been done for this copper complex.

The Commission indicated that the provision on the MRL requirement proposed in the draft opinion was never included in approval regulations for PT08, and should therefore be removed. The absence of the provision would in any case not prevent establishing MRLs in case of need, depending on the outcome of the discussions on MRLs setting.

The rapporteur and some members considered that the provision could however be useful, and pleaded to keep it.

The AR was agreed by the BPC, subject to the changes agreed during the meeting. The opinion was adopted by majority (one member having a minority position). The member from DK abstained due to disagreement with the use of an assessment factor of 1 used for the derivation of some PNEC values. The members from SE and NO expressed their disagreement with the use of the assessment factor of 1.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 21 January 2016.
- **Member:** to provide its minority position in writing to the SECR by 18 December 2015.
- **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 January 2016 and publish it on the ECHA website.

7.10 Draft BPC opinion on tolylfluanid for PT 7

The Chairman informed the meeting that no applicant was present for this item.

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).

The main discussion topic was the restricted outdoor use for window, door frames and doors. The rapporteur explained that the restricted use is safe for professional and non-professional users and the environment. The rapporteur clarified the choice of the model (outdoor vs indoor) used and the exposure calculations made. This was commented on by some members. The SECR confirmed that the outdoor model was the appropriate choice considering the scenarios.

The rapporteur also explained that there was a risk identified for the environment due to a degradation product of tolylfluanid. A member requested further restrictions on the placing on the market and use of treated articles with tolylfluanid. However, no additional restriction was proposed as the proposed risk mitigation measures were considered as acceptable.

Due to the unacceptable environmental risks identified for industrial application and storage one member proposed to include the respective standard phrase which is used for PT 8. However, the majority of the BPC was of the opinion that this RMM was not relevant for the uses assessed (windows and door frames).

The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. One member abstained.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 21 January 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 January 2016 and publish it on the ECHA website.

7.11 Draft BPC opinion on L(+) lactic acid for PT 1

The Chair noted that the applicant was not present during the meeting.

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).

The risk characterisation for professionals and non-professionals due to the eye damaging properties of the active substance was the main topic for discussion.

For professional use, the rapporteur clarified that the use of the biocidal product for face washing should be considered as accidental exposure and that non-acceptable risks for local effects had not been identified for the professional users. For the non-professional

users, the use of the biocidal product for face washing should be considered as a realistic misuse leading to a non-acceptable risk due to the classification of the representative product as H318.

It was then proposed that for the authorisation of biocidal products, eye irritation tests could be conducted with the actual product to clarify its eye damaging properties or a lower content of the active substance could be used in the biocidal product in order to avoid the classification as H318.

The AR for L(+) Lactic acid in PT1 was agreed by the BPC, subject to the changes agreed during the meeting.

Next the BPC discussed the opinion. A similar discussion and agreement regarding the use of the hand soap took place and other comments from MSs and the SECR were taken into account.

The BPC adopted by consensus its opinion on the application for approval of the active substance L(+) Lactic acid for its use in PT 1.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 21 January 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 January 2016 and publish it on the ECHA website.

7.12 Draft BPC opinion on *Bacillus amiloliquefaciens* strain ISB06 for PT 3

The Chair noted that the applicant was not present during the meeting.

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).

A member considered that the microbial contaminants are part of the identity of the microbial active substance and should normally be part of the active substance approval. However, the member could accept the data to be submitted for product authorisation. The rapporteur explained that this would be a completely new data requirement worldwide, as contaminant levels refer to the actual products. This information is essential for the residues in food and feed, but does not give relevant information on the microbial active substance itself.

It was agreed to summarize data requirements for the representative product in a separate chapter of the assessment report. In this context, it was clarified, that this does not apply for efficacy data as efficacy has to be proven anyway at product authorisation stage for all products.

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

The BPC adopted by consensus its opinion on an application for the approval of *Bacillus amiloliquefaciens* strain ISB06 for its use in PT 3.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 21 January 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 January 2016 and publish it on the ECHA website.

7.13 Draft BPC opinion on formaldehyde for PT 3

The Chairman welcomed the applicants for this item. The Chairman noted that the applicants 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).

For some of the scenarios described in the opinion the eCA used the term "trained professionals" for the exposed group. The BPC discussed the use of this term in the opinion. Many members as well as SECR commented that as the term "trained" is used in the national legislation of some MS but not in all, it may create confusion in a document reflecting the outcome of the peer review process. For consistency with other evaluations, it was suggested to remove the word "trained" from the text of the opinion and instead add a footnote with some explanation referring to "professionals adequately trained".

The BPC also discussed the proposed additional paragraph summarising the outcome of the public consultation. Many members commented that the wording of the opinion cannot suggest that the rapporteur or BPC evaluated the information received during the public consultation stage as that has not been done. The BPC so far has not had a critical look at all comments received during the public consultation period. The rapporteur explained that their experience so far shows that the kind and quality of the submitted information does usually not allow a real evaluation and conclusion neither by the eCA nor by the BPC. The Commission regretted this current lack in the work of the BPC. It was decided that the tasks of the BPC with regard to assessing these comments will need to be addressed in the context of a separate, more general discussion.

The substance is considered as a candidate for substitution in accordance with Article 10(1)(a) of the BPR.

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

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 21 January 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 January 2016 and publish it on the ECHA website.

7.14 Draft BPC opinion on cyromazine for PT 18

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

The Chairman clarified that the substance was previously discussed at BPC 11 and due to inconsistencies in the environmental risk assessment, the CAR was submitted to environmental working group to review the changes made. The Chairman invited the rapporteur to explain the main changes done from the last version of the opinion and AR.

In regards to the use of the time weighted average approach for the environmental risk assessment the Chair of the environmental working group clarified that the approach used has already been discussed at different forums as it is considered not to be the most appropriate method. Nevertheless, it has been used for all the PT18 active substances and products evaluated so far. The item has been taken up in the frame of a recommendation for the PT18 emission scenario document and it is also a high priority item for the first revision of Volume IV part B which will take place during 2016. The Chairman stated that there will be guidance before product authorisation. The BPC members agreed that the AR can remain as it is because the agreed guideline is not yet ready.

One member mentioned that the input values and the specific parameters used for the exposure calculations are not present in the AR and therefore it is difficult to follow what has been done. The rapporteur agreed to include the relevant information in the AR.

One member indicated that even though the Working Group Human Health has discussed the issue and reached a conclusion, the member still is of the opinion that the data available show that the substance has the potential to cause gene mutations both in-vivo and in-vitro. The member stated that the available indication should have not been neglected and will not support the approval of the substance.

COM considered that because the substance is classified as vP it should not be eligible for Annex I inclusion in line with article 28.2 of the BPR referring to equivalent level of concern. COM mentioned that this approach is not yet included in a guidance document, but follows the logic pursued in the area of treated articles, where additional requirements on the labelling of treated articles were agreed with Member States due to general concerns on vP substances.

One member mentioned that secondary exposure for children has not been assessed while it is stated in the opinion that it may be used in and around areas where children are. The member suggested to add a safety phrase that children should not have access

to the application area or otherwise a risk characterization should be performed. The applicant requested further guidance in regards to the duration when access to children should be prohibited. The rapporteur agreed to add the safety phrase.

The opinion was adopted by majority with the minority opinion of one member.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 21 January 2016.
- **Member:** to provide its minority position in writing to the SECR by 18 December 2015.
- **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 January 2016 and publish it on the ECHA website.

7.15 Update on Union Authorisations applications

SECR presented the current status of the applications for Union authorisation received by ECHA and the on-going preparatory activities. One member mentioned that the commenting period on the draft assessment prepared by the eCA is short: 28 days. The member therefore recommended that the SECR informs the members in time of the start of the commenting phase. SECR explained that the 28 days are a first proposal and that this period might be extended if really needed. A member asked if there will always be a need for a discussion at Working Group level. SECR stated that this was included in the working procedure to: i) solve any technical issues before the discussion at the BPC; ii) build-up expertise in the Working Groups on Union authorisation. SECR recommended to keep the Working Group discussions in for the first applications where in due time it may be considered on a case-by-case basis to directly discuss assessments at the BPC.

Actions:

- **Members:** to send comments and proposals for updating the Working Procedure for Union Authorisation via the CIRCABC newsgroup by 15 January 2016.
- **SECR:** to prepare a revised version of the WP for Union Authorisation in light of the information from members and experience gained.

7.16 Follow-up on the Workshop "Reviewing the active substance assessment process"

a) Applicability of new guidance and guidance related documents

SECR presented the new version of the document and explained the main changes made since the last version. The members had some comments and requested some clarifications mostly in regards to the differentiation made between guidance for product authorisation and guidance for active substance and the timelines for application defined

in section 2.2 of the document. SECR explained that the main difference lies in the fact that active substance applications were submitted long ago, and there was a need to harmonise all dossiers instead of trying to know which guidance was available at the time of submission of the dossiers or the CARs. SECR agreed to re-structure the document focusing on point 2.2 and avoiding confusion with point 2.1 (general rules).

In general the members appreciated the new version of the document and there was a general agreement to proceed with the finalisation once all new comments have been implemented.

Actions:

- **SECR:** to revise the document in light of the discussion and upload the final version to CIRCABC IG and the ECHA website.

b) The role of the BPC Secretariat in the active substance approval process

The Chairman introduced the new version of the document. Members welcomed the document and found it helpful to better define the roles of the different parties in the active substance approval process. Following a question from a member, the Chairman recommended to discuss in principle the evaluations for the "back-log dossiers" at all the Working Groups.

Actions:

- **SECR:** to finalise the document and upload to CIRCABC IG.

c) Possibility of introducing new data or new information during the peer review process

The Chairman introduced the document. Members asked clarification on: i) public consultation where it was recommended to state more clearly that sometimes information is submitted on the active substance itself, but that this is not the purpose of the public consultation; ii) clarifying the paragraph on the backlog dossiers and indicating that only in exceptional cases dossiers can be put on hold. With these changes the document was agreed.

One member asked if the condition (for being able to submit additional data) that the 270 day time limit must be adhered to, should be interpreted strictly. This was confirmed by the Chairman: the 270 days, which is a legal time line specified in the BPR, must be respected. Following this it was discussed if this has consequences for the scope of the Working Group discussions, meaning that risk mitigation shall also be included in the scope of these discussions. It was mentioned by some members that this is difficult, as there are normally changes agreed at the Working Group impacting the risk assessment. As a consequence, the outcome of the evaluation is in many cases unknown before and during the Working Group discussions. The SECR indicated that currently risk mitigation "as such" and the validity of risk mitigation measures is not discussed at the Working Groups. The Chairman indicated that it is preferred that at the Working Groups the

overall conclusion of the evaluation is considered and discussed, taking into account the original proposal and (as much as possible) the foreseen changes to the risk assessment. More discussion on this aspect may be required, as Working Groups have a responsibility in evaluating and reviewing the proposal for risk mitigation measures (i.e. Working Groups should be a source of proposals for appropriate and realistic risk mitigation measures).

One member mentioned that another source for data may be a submission under Article 95 by an alternative supplier. Reference was made to a situation related to a CLH dossier, where the MSCA has to consider according to the CLP "all readily available information". The member asked if the MSCA is allowed to use this information contained in an Article 95 submission. The Chairman noted this and indicated ECHA will come back to it at the next meeting.

Actions:

- **SECR:** to revise the document in light of the discussion and upload the final version to CIRCABC IG and the ECHA website.

8. Any other business

8.1 Update on harmonising the dossier format between biocides and harmonised classification and labelling under CLP

Following a question from a member the Chairman informed the meeting that ECHA will establish in the beginning of 2016 a task force consisting of Members State Competent Authorities (MSCA) CLP and BPR representatives and ECHA, with the scope of harmonising the CAR and CLH templates in order to facilitate the work within both frameworks. It was stated that following a meeting in Brussels and two workshops on the relation between CLP and PPP/BPR, several actions were agreed upon. The SECR will inform the meeting of the state-of-play at the next BPC considering the reporting alreadt provided at RAC by ECHA.

Actions:

- **SECR:** to provide an overview at BPC-14 on the status of harmonising the templates and on other actions undertaken by ECHA.

8.2 Update on guidance development related to in-situ generated active substances

Following a request from a member the Chairman informed the meeting that ECHA is developing guidance on how to establish the reference specification for in-situ generated active substances, which is not relevant for the generated active substance but more for the precursor(s). This guidance will be discussed within the APCP Working Group. It was agreed that other topics where guidance may be needed will be forwarded by the members to the SECR.

Actions:

- **SECR:** to consider further guidance development.
- **Members:** to inform the SECR on the need for further guidance developments.

8.3 Information on work sharing proposal of SECR presented at the Human Health and Environment working groups

Following a request from some members, the Chair of the Human Health Working Group introduced the document "Tackling the workload in WG meetings in 2016" which was presented at the Human Health and the Environment Working Group in November. The document was prepared by the SECR due to the expected high workload for the II – IV Working Group meetings in 2016 and contains some general suggestions, a proposal on work sharing and organisational proposals. The document is aimed at tackling the upcoming workload to guarantee that sufficient commenting on draft CARs takes place in the peer review process. It is expected that at least the core members are commenting according to the work sharing proposal presented.

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 13th meeting of BPC

8-11 December 2015

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 without further changes. Three items were added to the agenda item AOB: - Update on harmonising the dossier format between biocides and harmonised classification and labelling under CLP; - Update ECHA on guidance development related to in-situ generated active substances; - Information on work sharing proposal of SECR presented at Human Health and Environment working groups.	**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-12	
The revised version of the minutes of BPC-12 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	
5.3 Revised BPC Working Procedure	
The revised working procedure, reflecting the future use of R4BP for formal communication and exchange of documents between SECR, eCAs and applicants was agreed as proposed.	**SECR:** to upload the revised version to the ECHA website **SECR:** to consider how the communication tool function of R4BP 3 can be improved.
Item 6 - Work programme for BPC	
6. a) Revised Work Programme 2015-2016	
Priority shall be given to the first and second priority list substances of the Review Programme Regulation.	**Members:** to send information on any further changes to the Work Programme (WP) to the SECR **by 18 December 2015**. **SECR:** on the basis of the changes to update the WP on the ECHA web site and in the BPC CIRCABC IG. **SECR**: to contact eCAs to have an overview on the status of the second priority list substances.

Item 7 - Applications for approval of active substances	
7.2 Draft BPC opinion on Bardap 26 for PT 8	
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 discussions in the BPC and submit to the SECR **by 21 January 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 January 2016** and publish it on the ECHA website.
7.3 Draft BPC opinion on DBDCB for PT 6	
The BPC adopted by consensus the opinion for the approval of this active substance/PT combination. One member abstained.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 12 February 2016.** **Rapporteur:** to send to SECR a document on the derivation of AELs for discussion at the first WG Human Health of 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 January 2016** and publish it on the ECHA website.
7.4 Draft BPC opinion on Ampholyt for PT 2 and PT 4	
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 discussions in the BPC and submit to the SECR **by 21 January 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 January 2016** and publish it on the ECHA website.
7.5 Draft BPC opinion on biphenyl-2-ol for PT 3	
The BPC adopted by consensus its opinion on an application 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 21 January 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 January 2016** and publish it on the ECHA website.
7.6 Draft BPC opinion on copper thiocyanate for PT 21	

The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. One member abstained.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 21 January 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 January 2016** and publish it on the ECHA website. **SECR:** to initiate workshop on performing and assessing dermal absorption studies for antifouling paints.
7.7 Draft BPC opinion on coated copper flake for PT 21	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. One member abstained.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 21 January 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 January 2016** and publish it on the ECHA website.
7.8 Draft BPC opinion on dicopper oxide (cuprous oxide) for PT 21	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. One member abstained.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 21 January 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 January 2016** and publish it on the ECHA website. **SECR:** to clarify if technical equivalence assessment is required when the impurity level is lower than the maximum content specified in the reference specification but higher than the content set in the specification for the reference source.
7.9 Draft BPC opinion on granulated copper for PT 8	
The BPC adopted by majority its opinion on an application for the approval of this active substance/PT combination. One member abstained. One member did not support the opinion.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 21 January 2016.** **Member:** to provide its minority position in writing to the SECR by **18 December 2015**. **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 January 2016 and publish it on the ECHA website.
7.10 Draft BPC opinion on tolylfluanid for PT 7	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. One member abstained.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 21 January 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 January 2016** and publish it on the ECHA website.
7.11 Draft BPC opinion on L(+) lactic acid for PT 1	
The BPC adopted by consensus its opinion on an application 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 21 January 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 January 2016** and publish it on the ECHA website.
7.12 Draft BPC opinion on *Bacillus amiloliquefaciens* for PT 3	
The BPC adopted by consensus its opinion on an application 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 21 January 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 January 2016** and publish it on the ECHA website.
7.13 Draft BPC opinion on formaldehyde for PT 3	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. The substance is considered as a candidate for substitution in accordance with Article 10(1)(a) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 21 January 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 January 2016** and publish it on the ECHA website.
7.14 Draft BPC opinion on cyromazine for PT 18	
The BPC adopted by majority its opinion on an application for the approval of this active	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and

substance/PT combination. One member did not support the opinion.	submit to the SECR **by 21 January 2016.** **Member:** to provide its minority position in writing to the SECR by **18 December 2015**. **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 January 2016** and publish it on the ECHA website.
7.15 Update on Union Authorisation applications	
	Members: to send comments and proposals for updating the Working Procedure for Union Authorisation via the CIRCABC newsgroup **by 15 January 2016.** **SECR:** to prepare a revised version of the WP for Union Authorisation in light of the information from members and experience gained.
7.16 Follow-up on the Workshop "Reviewing the active substance assessment process"	
7.16 a) Applicability of new guidance and guidance related documents	
The document with the changes discussed was agreed by the BPC. Members were requested to consider allocation of resources to contribute to guidance development (including Ad hoc WG recommendatons) on environmental and human exposure.	**SECR:** to revise the document in light of the discussion and upload the final version to CIRCABC IG and the ECHA website.
7.16 b) The role of the BPC Secretariat in the active substance approval process	
	SECR: to finalise the document and upload to CIRCABC IG.
7.16 c) Possibility of introducing new data or new information during the peer review process	
The document with the changes discussed was agreed by the BPC.	**SECR:** to revise the document in light of the discussion and upload the final version to CIRCABC IG and the ECHA website.
Item 8 – Any other business	
8.1 Update on harmonising the dossier format between biocides and harmonised classification and labelling under CLP	
	SECR: to provide an overview at BPC-14 on the status of harmonising the templates and on other actions undertaken by ECHA.
8.2 Update on guidance development related to in-situ generated active substances	
SECR informed that the APCP working group is developing guidance on setting the reference specification for in-situ generated substances and	**SECR:** to consider further guidance development. **Members**: to inform the **SECR** on the need for

their precursor(s). Currently no other guidance development is foreseen at ECHA.	further guidance developments
8.3 Information on work sharing proposal of SECR presented at Human Health and Environment working groups	
The SECR informed the meeting on the proposal.	

Part III - List of Attendees

Members	European Commission
BORGES Teresa (PT)	CHATELIN Ludovic (DG SANTE)
BROVKINA Julija (LV)	NAGTZAAM Martinus (DG SANTE)
ČEBAŠEK Petra (SI)	
CHÉZEAU Aurélie (FR)	**Advisers**
COSTIGAN Michael (UK)	COLLETT GORDON Suzanne (NO)
DONS Christian (NO)	ENSCH Svenja (LU)
DRAGOIU Mihaela-Simona (RO)	GONZALEZ GONZALEZ Lorena (ES)
GONZALEZ MARQUEZ Luisa (ES)	HÄMÄLÄINEN Anna-Maija (FI)
HAHLBECK Edda (SE)	KANDRIS Ioannis (EL)
HARRISON John (IE)	LEBLOND Annabelle (FR)
JÄGER Stefanie (DE)	MEDJO-BYABOT Corettie (FR)
KOMEN Corine (NL)	PASANEN Jaana (FI)
LARSEN Jørgen (DK)	PALOMÄKI Jaana (FI)
MIKOLASKOVA Denisa (SK)	PLATTNER Edmund (AT)
RUBBIANI Maristella (IT)	RAMOS SCHLEGEL Carmen (ES)
SPATNY Nina (AT)	RITZ Vera (DE)
SZÁNTÓ Emese (HU)	WEINHEIMER Viola (DE)
TUUSA Tiina (FI)	**Accredited Stakeholder Organisations**
VAN BERLO Boris (BE)	LEROY Didier (CEPE)
VRHOVAC FILIPOVIC Ivana (HR)	REID Kirsty (Eurogroup for Animals)
ZIGRAND Jeff (LU)	
ZOUNOS Athanasios (EL)	**ECHA Staff**
	AIRAKSINEN Antero
Alternate members	ANTAL Diana
GAVRIEL Alexandros (CY)	ESTEVAN MARTINEZ Carmen
KULD Piret (EE)	GUTIERREZ ALONSO Simon
MIKOLAS Jan (CZ)	JANOSSY Judit
PYTHON François (CH)	NEGULICI Ligia
	PECORINI Chiara
Invited expert	SCHIMMELPFENNIG Heike
HUSZAL Sylwester (PL)	VAN DE PLASSCHE Erik

Applicants	Apologies
ATKIN Charles (Arch Timber Protection) for granulated copper PT 8	CAZELLE Elodie (AISE)
DORNIEDEN Hiltrud (Novartis Animal Health/Elanco) for cyromazine PT 18	GIORDMAINA Wayne (MT)
GROTH Torsten (Lanxess Duetschland GmbH) for DBDCB PT 6	MAJUS Saulius (LT)
LEONHARDT Wolfgang (Evonik Nutrition & Care GmbH) for Ampholyt PT 2 and 4	
MACKIE Carol (Regulatory Compliance Ltd) for Bardap 26 PT 8, copper thiocyanate PT 21, coated copper flake PT 21, cuprous oxide PT 21	
MUNK Wolfgang (Hokochimie Sarl) for cyromazine PT 18	
RÖRTGEN Sherin (Ewabo Chemikalien) for formaldehyde PT 3	
STROECH Klaus (Lanxess Deutschland GmbH) for biphenyl-2-ol for PT 3	
WIDULLE Herbert (Interhygiene GmbH) for formaldehyde PT 3	
Experts accompanying applicants	
BITSCH Annette, accompanying RÖRTGEN Sherin, for formaldehyde PT 3	
BLAISE Christian, accompanying MUNK Wolfgang, for cyromazine PT 18	
LONG Kevin, accompanying MACKIE Carol, for copper thiocyanate PT 21, coated copper flake PT 21, cuprous oxide PT 21	
MACKIE Carol, accompanying ATKIN Charles, for granulated copper PT 8	
MILLER Natalie, accompanying DORNIEDEN Hiltrud, for formaldehyde PT 3	
TOMASGAARD Lars, accompanying MACKIE Carol, for copper thiocyanate PT 21, coated copper flake PT 21, cuprous oxide PT 21	
WERNER Michael, accompanying GROTH Torsten, for DBDCB PT 6	

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-13

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-13 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2	BPC-A-13-2015	Draft agenda	
4	BPC-M-12-2015	Draft minutes from BPC-12	
5.2	BPC-13-2015-01	Administrative issues and report from the other Committees	
5.3	BPC-13-2015-02	Updated BPC Working Procedure	
6.1a)	BPC-13-2015-03	BPC updated Work Programme 2015-2016	
6.1b)	BPC-13-2015-04	Outlook	
6.1c)	BPC-13-2015-05	Backlog dossiers project	
7.15	BPC-13-2015-06	Status of Union Authorisations	
7.16a)	BPC-13-2015-07	Applicability of new guidance and guidance related documents	
7.16b)	BPC-13-2015-08	The role of the BPC Secretariat in the active substance approval process	
7.16c)	BPC-13-2015-09	Possibility of introducing new data or new information during the peer review process	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.2	BPC-13-2015-10A	Bardap 26 PT 8	Draft opinion
	BPC-13-2015-10C		Open issues
7.3	BPC-13-2015-11A	DBDCB PT 6	Draft opinion
	BPC-13-2015-11C		Open issues
7.4	BPC-13-2015-12A	Ampholyt PT 2	Draft opinion
	BPC-13-2015-12C		Open issues
7.4	BPC-13-2015-13A	Ampholyt PT 4	Draft opinion
	BPC-13-2015-12C		Open issues
7.5	BPC-13-2015-14A	Biphenyl-2-ol PT 3	Draft opinion

	BPC-13-2015-14B		Assessment report
	BPC-13-2015-14C		Open issues
7.6	BPC-13-2015-15A	Copper thiocyanate PT 21	Draft opinion
	BPC-13-2015-15A_rev		Revised draft opinion
	BPC-13-2015-15B		Assessment report
	BPC-13-2015-15C		Open issues
7.7	BPC-13-2015-16A	Coated copper flake PT 21	Draft opinion
	BPC-13-2015-16A_rev		Revised draft opinion
	BPC-13-2015-16B		Assessment report
	BPC-13-2015-16C		Open issues
7.8	BPC-13-2015-17A	Cuprous oxide PT 21	Draft opinion
	BPC-13-2015-17A_rev		Revised draft opinion
	BPC-13-2015-17B		Assessment report
	BPC-13-2015-17C		Open issues
7.9	BPC-13-2015-18A	Granulated copper PT 8	Draft opinion
	BPC-13-2015-18B		Assessment report
	BPC-13-2015-18C		Open issues
7.10	BPC-13-2015-19A	Tolylfluanid PT 7	Draft opinion
	BPC-13-2015-19B		Assessment report
	BPC-13-2015-19C		Open issues
	BPC-13-2015-19D		Proposal from eCA on Sections 2.3, 2.4 of opinion
7.11	BPC-13-2015-20A	(L)+ lactic acid PT 1	Draft opinion
	BPC-13-2015-20B		Assessment report
	BPC-13-2015-20C		Open issues
7.12	BPC-13-2015-21A	*Bacillus amyloliquefaciens* PT 3	Draft opinion
	BPC-13-2015-21B		Assessment report
	BPC-13-2015-21C		Open issues
7.13	BPC-13-2015-22A	Formaldehyde PT 2	Draft opinion
	BPC-13-2015-22B		Assessment report
	BPC-13-2015-22C		Open issues
7.13	BPC-13-2015-23A	Formaldehyde PT 3	Draft opinion
	BPC-13-2015-23B		Assessment report
	BPC-13-2015-23C		Open issues
7.14	BPC-13-2015-24A	Cyromazine PT 18	Draft opinion
	BPC-13-2015-24B		Assessment report
	BPC-13-2015-24C		Open issues

BPC-A-13-2015_rev1

Final agenda
13th meeting of the Biocidal Products Committee (BPC)
8 – 11 December 2015
ECHA Conference Centre, Annankatu 18, Helsinki
8 December: starts at 13:30
11 December: ends at 13:00

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-13-2015_rev1

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-12

BPC-M-12-2015

For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

BPC-13-2015-01

For information

5.3 Updated BPC working procedure

BPC-13-2015-02

For agreement

6. – Work programme for BPC

6.1. BPC Work Programme

a) Revised BPC Work Programme 2015-2016

BPC-13-2015-03

For information

b) Outlook

BPC-13-2015-04

For information

c) Backlog dossiers project

BPC-13-2015-05

For information

7. – Applications for approval of active substances*

7.1. Templates and formats for active substance approval

a) Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval (introducing the new wording of the conditions for active substance approval)

For information

7.2. Draft BPC opinion on Bardap 26 for PT 8

Previous discussion(s): TM III- 2009, BPC-9 and BPC-12

BPC-13-2015-10A, B and C

For adoption

7.3. Draft BPC opinion on DBDCB for PT 6

Previous discussion(s): 2010 TM IV, WG-III-2015 and BPC-12

BPC-13-2015-11A and C

For adoption

7.4. Draft BPC opinion on Ampholyt for PT 2 and 4

Previous discussion(s): WG-III-2014, BPC-8 and BPC 12

PT 2: BPC-12-2015-12A and C

PT 4: BPC-12-2015-13A and BPC-13-2015-12C

For adoption

7.5. Draft BPC opinion on biphenyl-2-ol for PT 3

Previous discussion(s): WG-V-2014, BPC-9 and BPC-11

BPC-13-2015-14A and C

For adoption

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* 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).

7.6. Draft BPC opinion on copper thiocyanate for PT 21

Previous discussion(s): WG-IV-2015

BPC-13-2015-15A, B and C

For adoption

7.7. Draft BPC opinion on coated copper flake for PT 21

Previous discussion(s): WG-IV-2015

BPC-13-2015-16A, B and C

For adoption

7.8. Draft BPC opinion on cuprous oxide for PT 21

Previous discussion(s): WG-IV-2015

BPC-13-2015-17A, B and C

For adoption

7.9. Draft BPC opinion on granulated copper for PT 8

Previous discussion(s): WG-IV-2015

BPC-13-2015-18A, B and C

For adoption

7.10. Draft BPC opinion on tolylfluanid for PT 7

Previous discussion(s): WG-IV-2015

BPC-13-2015-19A, B and C

For adoption

7.11. Draft BPC opinion on (L)+ lactic acid for PT 1

Previous discussion(s): WG-IV-2015

BPC-13-2015-20A, B and C

For adoption

7.12. Draft BPC opinion on *Bacillus amyloliquefaciens* for PT 3

Previous discussion(s): WG-III-2015

BPC-13-2015-21A, B and C

For adoption

7.13. Draft BPC opinion on formaldehyde for PT 3

Previous discussion(s): TM-I-2012

PT 3: BPC-13-2015-23A, B and C

For adoption

7.14. Draft BPC opinion on cyromazine for PT 18

Previous discussion(s): TM-II-2012, WG-I-2015 and BPC-11

BPC-13-2015-24A, B and C

For adoption

7.15. Update on Union Authorisation applications

BPC-13-2015-06

For information

7.16. Follow-up on the Workshop "Reviewing the active substance assessment process":

a) Applicability of new guidance and guidance related documents

BPC-13-2015-07

For agreement

b) The role of the BPC Secretariat in the active substance approval process

BPC-13-2015-08

For information

c) Possibility of introducing new data or new information during the peer review process

BPC-13-2015-09

For agreement

Item 8 – Any other business

8.1 Update on harmonising the dossier format between biocides and harmonised classification and labelling under CLP

For information

8.2 Update ECHA on guidance development related to in-situ generated active substances

For information

8.3 Information on work sharing proposal of SECR presented at Human Health and Environment working groups

For information

Item 9 – Agreement of the action points and conclusions

For agreement

Provisional timeline for the

13th meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Annankatu 18, Helsinki

8 December 2015: starts at 13:30
11 December 2015: 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. Morning sessions usually start at 09:00.

Tuesday 8 December: afternoon session

Items 1-5	Opening items and administrative issues
Item 6	Work programme a) Revised BPC Work Programme 2015-2016 b) Outlook c) Backlog dossiers project
Item 7.1	Templates and formats for active substance approval a) Catalogue of specific conditions and elements to be taken into account at the product authorisation stage
Item 7.2	Draft BPC opinion on Bardap 26 for PT 8
Item 7.3	Draft BPC opinion on DBDCB for PT 6
Item 7.4	Draft BPC opinion on Ampholyt for PT 2 and 4
Item 7.5	Draft BPC opinion on biphenyl-2-ol for PT 3

Wednesday 9 December: morning session

Item 7 (cont'd)	Follow up to previous discussions on draft substance opinions
Item 7.6	Draft BPC opinion on copper thiocyanate for PT 21
Item 7.7	Draft BPC opinion on coated copper flake for PT 21
Item 7.8	Draft BPC opinion on cuprous oxide for PT 21
Item 7.9	Draft BPC opinion on granulated copper for PT 8

Wednesday 9 December: afternoon session

Item 7.10	Draft BPC opinion on tolylfluanid for PT 7
Item 7.11	Draft BPC opinion on L(+) lactic acid for PT 1

Thursday 10 December: morning session

Item 7 (cont'd)	Follow up to previous discussions on draft substance opinions
Item 7.12	Draft BPC opinion on *bacillus amyloliquefaciens* for PT 3
Item 7.13	Draft BPC opinion on formaldehyde for PT 3

Thursday 10 December: afternoon session

Item 7.13 (cont'd)	Draft BPC opinion on formaldehyde for PT 3
Item 7.14	Draft BPC opinion on cyromazine for PT 18

Friday 11 December: morning session

Item 7 (cont'd)	Follow up to previous discussions on draft substance opinions
Item 7.15	Update on Union Authorisations applications
Item 7.16	Follow-up on the Workshop "Reviewing the active substance assessment process": a) Applicability of new guidance and guidance related documents b) The role of the BPC Secretariat in the active substance approval process c) Possibility of introducing new data or new information during the peer review process
Item 8	AOB
Item 9	Agreement of the action points and conclusions

End of meeting

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