14 February 2017
BPC-M-18-2016

Final minutes of the 18th meeting of the Biocidal Products Committee (BPC)

13 – 16 December 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 18th BPC meeting and informed the meeting that no changes occurred recently in the BPC membership.

The Chairman informed the BPC members of the participation of 25 members, including six alternates.

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

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-18-2016_rev3) and invited then any additional items. No additional items were added to the agenda.

The agenda was then adopted. 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-17

The revised draft minutes from BPC-17 (BPC-M-17-2016), incorporating the comments received from members, were agreed.

The Chairman informed the BPC members on the establishment of the Ad hoc Working Group on Microorganisms with 14 members.

Furthermore, the Chairman announced a BPC commenting round for the revised REACh guidance on PBT assessment as well as for the combined CLH/CAR template.

As follow-up of the discussion on PHMB, PT 5 (risk assessment for livestock and domestic animals), ECHA is preparing a document for the next CA meeting with regard to animal safety.

Actions:

- **SECR:** to upload the agreed minutes from BPC-17 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-18-2016-01 covering the administrative updates and the report form the other ECHA Committees, provided to members for information purposes. The Chairman mentioned that the next report will also include the updates from the PBT Expert Group and 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 a total of 41 opinions for the Review Programme and 5 for new active substances from the BPD for 2016. As concerns the workload foreseen for 2017 and reflected in the "Outlook for BPC" document, the Chairman mentioned that the main workload will still be represented by active substances, with most opinions scheduled for the last two meetings of the year. The first Union authorisation opinions are likely to be scheduled for the last BPC meeting in 2017. One additional Article 75(1)(g) request has been included in the document, related to the use of copper sulfate in PT 3. With regard to the second priority list dossiers, the Chairman informed the meeting that, according to the latest information available, 62 of the 97 remaining dossiers will not be submitted by the deadline (31 December 2016). With respect to the first priority list, 27 dossiers have not yet been finalized but most of them are expected to be finalized by the end of 2017.

The Commission expressed concerns concerning the report made about the 2nd priority list, and invited Member States to take necessary measures to limit the delay to the minimum. Collective objectives were decided back in 2013-2014, and Member States must ensure that actions are taken so that they can be met.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) to the SECR **by 22 December 2016**.
- **SECR**: on the basis of the changes to update the work programme on the ECHA web site and in the BPC CIRCABC IG.

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 informed the meeting that no changes were made after the last BPC meeting.

7.2 Draft BPC opinion on peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate for PTs 2, 3 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 rapporteur introduced the substance and the general issues related to the assessment reports (AR) and opinions were then discussed in detail (modifications are described in the open issues table).

There were discussions on a possible requirement for specific ratio of both precursors and the need for MRLs for the precursors. It was concluded that no specific ratio for the precursors needs to be indicated after the applicant explanation on the excess presence of sodium per carbonate (SPC) to ensure the complete transformation of the other precursor (TAED) into peracetic acid (PAA). No conclusion could be reached on the need and feasibility for setting MRLs for precursors. SECR will investigate and discuss further with COM.

Regarding the specifications of the precursor TAED, it was precised that the minimum purity value for TAED is set at 99.0%. This value will be harmonised throughout all the documents. In the confidential annex, the minimum purity for each other potential source of TAED will be reported.

As general item, it was decided to include, from now on, a reaction scheme for all in-situ generated active substances in the identity part of the AR.

The Assessment Reports were agreed by the BPC, subject to the changes agreed during the meeting.

It was clarified that the chemical name, EC and CAS numbers of PAA, SPC and TAED should not be provided in the front page of the BPC Opinion in order to distinguish the "in-situ PAA" from the "non in-situ PAA". The Commission nevertheless indicated that

these elements will be needed in order to ensure clarity in the approval regulation about the identity of each substance (active substance, precursors).

The assessment of inhalation exposure to vapour of in-situ generated PAA will be required at the product authorisation step, as previously agreed at the technical meetings (TM IV 2013). However, for future dossiers this assessment should be provided, where relevant, already at the active substance approval stage.

ECHA proposed a new way of reporting information / conclusions related to indirect exposure via food in the opinions to answer in particular to the requests of a member on this aspect: from now on a subsection on the indirect dietary exposure via food should be included in the opinion of all active substances where dietary exposure via food is relevant. In absence of guidance it was decided that the standard phrase for requiring a dietary risk assessment (DRA) will be provided in section 2.4.

The BPC adopted by consensus the opinions for the approval of these active substance/PT combinations.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussion in the BPC and submit it to the SECR **by 27 January 2017.**
- **SECR:** to revise the draft opinions in accordance with the discussion in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 13 January 2017** and publish them on the ECHA website.

7.3 Draft BPC opinion on active chlorine released from sodium hypochlorite for PTs 1, 2, 3, 4 and 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 its uses in PT1, 2, 3, 4 and 5 and the issues related to the assessment report (AR) and to the opinion were then discussed in detail. The issues (general and specific to each PT) related to the assessment report (AR) were discussed first followed by the issues (general and specific to each PT) related to the opinions. The specific points discussed are summarised below. Agreed modifications are described in the open issues table.

Assessment report: general comments for all PTs

It was first discussed whether the analytical method to determine the relevant impurity sodium chlorate in the biocidal product should be added to the AR or to the opinion. The Chairman noted that the analytical method is related to the requested storage stability test to determine prior and after storage the content of sodium chlorate. A member raised the concern that the degradation product chlorate might be a stable metabolite; considering it a key aspect of the evaluation, the member said to consider that the analytical method should be included in the opinion. The rapporteur pointed out that the concentration of chlorates strictly depends on the concentration of the active substance

in the biocidal product, and that the analytical method is related to the composition of the biocidal product, hence a matter relevant for product authorisation; therefore the analytical method would not be of relevance to the opinion on the active substance but should instead be included in section 2.4 of the AR. Furthermore, as clarified by the Chairman, the analytical method is available therefore no requirement is needed in relation to this in section 2.5 of the opinion.

The request from a member to have the section "acceptable exposure scenarios" added to the list of endpoints (LoEP) was then addressed. Both the rapporteur and the SECR indicated not to agree with the proposal, pointing out that the section mentioned had been removed from the new version of the AR template as the LoEP should only reflect endpoints which are solely active substance related.

Referring to the request from the applicant to remove the aggregate risk assessment from the AR, the Chairman clarified that such risk assessment was required by the WG, hence it was included in the AR; however as it is not used for drawing conclusions on the active substance approval, it will not be included in the opinion. The Chair confirmed that the opinions and AR for the three substances will be harmonised in this respect.

Assessment report: PT2

The members discussed on the large difference between the use concentrations, expressed as available chlorine, for non-professional and professional use. The applicant agreed to investigate the reason why the non-professional use values are so much higher than those for the professional uses. The rapporteur will add the clarification if available before the finalisation of the AR.

Assessment report: PT3

A member requested an exposure estimation to chlorate (for livestock and human) from food and drinking water at product authorization for PT 3, 4 and 5. The member agreed to the clarification by the SECR that for PT 3 the EFSA CONTAM opinion is not considered relevant. However, the member requested a statement to be added to the AR indicating that the preliminary livestock exposure assessment performed for chlorate covers only the presence as an impurity from the manufacturing process and storage, but not the possible formation as a degradation product formed during use, as the formation of disinfectant by-products (DBP) was not taken into account in the assessment performed (DBP guidance under development). The member expressed concerns regarding the conclusion on the safe use given that is not possible to conclude in this situation that a worst case assessment has been done. The SECR added the clarification that livestock exposure assessment is relevant only for PT3 and PT5.

Assessment report: PT5

The request by a member to add a sentence on the risk/benefit analysis was discussed. Some members expressed their concern that the importance of the active substance in the disinfection of drinking water might not be considered during product authorisation, given the risks identified. The rapporteur argued that the risk/benefit analysis is not part of the active substance approval process. The Chairman clarified that the request to add such a statement is related to the fact that while the part of the EFSA CONTAM opinion related to the risks identified for children due to the chlorate had been added to the AR, the one related to the benefits had not been included. It was therefore agreed to include a also this part of the EFSA CONTAM opinion that "the potential concern for chlorate

residues in food has to be addressed in the context of the legislation on drinking water and/or food hygiene".

The comment by a member on the analytical method for residues in drinking water was discussed. The member asked to make it clear that at present there is no EU drinking water limit of 0.1 µg/L for chlorine. Another member also added that there is no EU drinking water limit for chlorate either. It was agreed to modify the AR accordingly.

BPC Opinion: general comments for all PTs

The request from several members to add the standard provision on the maximum residue levels (MRLs) to the opinions for PT 3, 4 and 5 was addressed. It was briefly discussed whether the MRLs should be set per PT or PT-independently. One member highlighted that should the provision be added to the opinions, something should be said also in relation to chlorates to ensure that when lowering the chlorate levels the microbiological food safety would not be compromised, but it was finally acknowledged that the definition of "residue" covers the active substance and all degradation products. The provision as proposed to be used for PT3, 4 and 5, was therefore agreed by the members.

Regarding the analytical methods mentioned in Section 2.5 the applicant stated that those can be made available to the eCA IT six months before the date of approval.

BPC Opinion: PT2

Related to the comment on the assessment for the environment the eCA clarified that the residence time before discharge of the effluent provided in the opinion is based on calculations. Furthermore, as a result of the discussion that followed on the specificity of the risk mitigation measures (which included labyrinths and an extended release pipe to increase the time available for degradation before release), and on the feasibility to enforce such measures, it was decided to amend the text in the opinions to allow for other measures that may ensure the same objective.

BPC Opinion: PT3

A member proposed some changes to the text, also to reflect the earlier discussions on the assessment report. It was agreed to add that the assessment was based on the presence of chlorate as an impurity, and refer the revision of the dietary risk assessment at product authorisation, if guidance becomes available (standard element to be added to section 2.4).

BPC Opinion: PT4

It was discussed whether a clarification on the conclusion (safe use or not) of the dietary risk assessment from the EFSA CONTAM Opinion should be added. It was concluded that the opinion should only reflect the outcome of the EFSA CONTAM Opinion, as requested at the Human Health Working Group.

On the request to add a reference to "bystanders" in section 2.3 and 2.4 it was agreed that "bystanders" would in this case also be professionals and therefore no amendment is needed.

BPC Opinion: PT 5

It was agreed to add a provision (in section 2.4) on the requirement for revising the dietary risk assessment at product authorisation, as was done for PT3

The BPC adopted by consensus the opinions for the approval for PTs 1, 2, 3, 4 and 5.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussion in the BPC and submit them to the SECR **by 27 January 2017.**
- **SECR:** to revise the draft opinions in accordance with the discussion in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 13 January 2017** and publish them on the ECHA website.

7.4 Draft BPC opinion on active chlorine released from calcium hypochlorite for PTs 2, 3, 4 and 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 its uses in PT2, 3, 4 and 5 and the issues related to the assessment report (AR) and to the opinion were then discussed in detail. The issues (general and specific to each PT) related to the assessment report (AR) were discussed first followed by the issues (general and specific to each PT) related to the Opinions. The specific points discussed are summarised below. Agreed modifications are described in the open issues table. For the points in common with active chlorine released from sodium hypochlorite the same conclusions were adopted without further discussion. When relevant, agreed changes for sodium hypochlorite will be reported in the documents related to calcium hypochlorite to ensure harmonisation.

Assessment report: PT2

The information that the non-professional products are dust-free tablets or granules will be included in the AR. Related to this non-professional use, several members reported that intoxications of private users have been registered by national poison centres, due to the storage of products in humid conditions. It was agreed to flag this issue in section 2.4 of the opinion so that it can be considered at product authorisation stage.

BPC Opinion: PT2

The relevance of having included in section 2.4 a reference to the assessment of the dummy product and its classification was discussed. Several members expressed the opinion that is sufficient to have that information in the AR for the product authorisation stage and therefore, the element was removed from the opinion.

The BPC adopted by consensus the opinions for the approval of PTs 2, 3, 4 and 5.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussion in the BPC and submit them to the SECR **by 27 January 2017.**
- **SECR:** to revise the draft opinions in accordance with the discussion in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 13 January 2017** and publish them on the ECHA website.

7.5 Draft BPC opinion on active chlorine released from chlorine for PTs 2 and 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 its uses in PT2 and 5 and the issues related to the assessment report (AR) and to the opinion were then discussed in detail. The issues (general and specific to each PT) related to the assessment report (AR) were discussed first followed by the issues (general and specific to each PT) related to the Opinions. The specific points discussed are summarised below. Agreed modifications are described in the open issues table. For the points in common with active chlorine released from sodium hypochlorite the same conclusions were adopted without further discussion. When relevant, agreed changes for sodium/calcium hypochlorite will be reported in the documents related to active chlorine released from chlorine to ensure harmonisation.

BPC Opinion: PT2

On two points raised by a member it was decided that: 1) the skin irritation H315 is to be added to the proposed classification; 2) the smell generating organisms mentioned as target species in the AR are considered to be covered by the organisms already listed in the opinion and do not need to be added.

BPC Opinion: PT5

The harmonisation with the opinions for active chlorine released from sodium and calcium hypochlorite in regards to the chlorate risk assessment, as requested by a member was discussed. It was noted that while chlorate is an impurity for sodium and calcium hypochlorite, it is not for chlorine. The chlorate risk assessment performed for sodium and calcium hypochlorite, covered only chlorate as an impurity. As there is no data for the chlorate formed during application/post-application of chlorine this was not covered in the risk assessment. This will be reflected in the opinion.

The BPC adopted by consensus the opinions for the approval for PTs 2 and 5.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussion in the BPC and submit them to the SECR **by 27 January 2017.**
- **SECR:** to revise the draft opinions in accordance with the discussion in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 13 January 2017** and publish them on the ECHA website.

7.7 Draft BPC opinion on acetamiprid 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). The Chairman informed the meeting that the public consultation, as acetamiprid is considered a potential candidate for substitution, is on-going until 17 January 2016. The intention is to include the results and adopt the opinion for acetamiprid via written procedure.

The rapporteur raised the issue that there was an ad-hoc follow up of the Human Health WG on the reference values for human health which did not lead to a consensus view. It was discussed how the BPC should proceed in this kind of situations. The possibility that the eCA needs to choose a value in order to finalise the assessment for the discussion at the BPC was not fully accepted. It was stated by several members that in such cases the BPC needs to decide on the value referring also to the working procedure. It was argued that in such cases the rapporteur has to present the case in advance of the BPC meeting analysing also the consequences of both options for the proposal for approval. It was agreed that the rapporteur will prepare a document in this respect which will be distributed for a written consultation to the BPC. Thereafter the assessment report and opinion will be amended, including also the results of the public consultation, and the opinion will be adopted via written procedure.

A general issue which was discussed was the meaning of the intended use table in the appendix of the AR. It was clarified that the table should clearly reflect what has been evaluated by the eCA.

Actions:

- **Rapporteur:** to provide SECR a document to launch a written consultation of the BPC on the selection of reference value and its impact on the assessment by **23 December 2016.**
- **SECR:** to launch the consultation via S-CIRCABC by **23 December 2016.**
- **Members:** to submit comments on the consultation as well as on the revised CAR by **13 January 2017.**

- **Rapporteur:** in cooperation with the SECR to prepare an amended version of the opinion including the outcome of the written consultation and the Public Consultation.
- **SECR:** to launch a written procedure for the adoption of the BPC opinion by **27 January 2017.**

7.8 Draft BPC opinion on MIT for PTs 11 and 12

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). The Assessment Reports were agreed with the modifications presented in the open issues table.

A member highlighted a general issue for PT 11 applications; the definition of "small" and "large" system is different in the ESD as compared to their national, regulatory definition. The issue may need to be further investigated as it may have implications for enforcement.

The main issue was related to PT 12. A slight exceedance of the PEC/PNEC ratio was found for the on-site sewage treatment plant (STP), which the rapporteur considered acceptable based on a weight of evidence (WoE) approach. The WoE was based on arguments including that: i) for the derivation of PNEC value the assessment factor (AF) applied was not reduced despite having more information; ii) instead of the geometric mean of the various studies, the lowest value was used; and iii) additional monitoring data indicating that the PEC is over-estimated. In addition, the rapporteur noted that the situation of an on-site STP of the paper production plant may be different compared to a municipal STP. This approach has not been reviewed or agreed by the ENV Working Group.

One member considered that according to point 74. Annex VI of the BPR, the PEC/PNEC ratio shall not be higher than 1. The SECR noted that there have been cases where the active was approved despite a slight exceedance of the ratio. The member questioned whether it is appropriate to consider "slight" exceedance different from exceedance.

The BPC decided to refer the following issues to the Environment Working Group: i) the possible reduction of the Assessment Factor for the derivation of the PNEC for the Sewage Treatment Plant; ii) the use of the monitoring data; iii) the weight of evidence approach.

With regards to dietary risk assessment the BPC concluded to follow the Human Health Working Group agreement to include only a statement that residue transfer to food is not relevant. Two members requested to clarify whether the scenario is relevant for other PT 12 actives. The rapporteur explained that the exposure assessment was performed to support that food exposure from this route is negligible and that the intention was to demonstrate that the exposure scenario is not relevant, as exposure is not expected. SECR added that exposure was negligible, well below the threshold value for livestock exposure, also in previous assessments carried out with other active substances in PT 12. A member noted

that their national legislation includes different recommendations for maximum amounts of slimicides present in cardboards or other types of paper that can come into contact with food and thus extrapolation from a limited data set may not be appropriate. It was concluded that it will be clarified whether the agreement of the working group is relevant for all PT 12 substances.

The BPC adopted by consensus the opinion for the approval of MIT in PT 11.

Actions:

PT 11:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 27 January 2017.**
- **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 **13 January 2017** and publish it on the ECHA website.

PT 12:

- **Rapporteur:** to provide SECR document to launch the written consultation of the ENV Working Group **by 19 December 2016**.
- **SECR:** to launch the written consultation of the ENV Working Group **by 19 December 2016**.

7.9 Draft BPC opinion on OIT 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 to the opinion were then discussed in detail (modifications are described in the open issues table).

A member commented that ARfD and ADI should be derived in case of additional uses that might lead to residues in food, as agreed during the Human Health WG V 2016 to derive always ADI and, if necessary, ARfD if appropriate information is available, unless it is not scientifically justified and to report them in the assessment report of each PT for which the active substance is under evaluation. As these values had not been derived for OIT in the absence of exposure, and to avoid a new discussion at WG level, it was agreed in that case not to follow the approach agreed in WG.

It was highlighted that the available information on relevant metabolites was not sufficient to conclude on the PBT status of the substance. Thus the PBT status may change, when information will become available for the metabolites.

Following the decision of the ENV Working Group, it was agreed to add in section 2.5 of the opinion a list of data needed to clarify the issue of unidentified but relevant metabolites.

The assessment report was agreed by the BPC. 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 it to the SECR **by 27 January 2017.**
- **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 13 January 2017** and publish it on the ECHA website.

7.10 Draft BPC opinion on MBIT for PT 13

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 informed that the outcome of the Environmental Working Group Ad hoc follow-up was the requirement of new degradation studies for three metabolites in order to refine the risk for the groundwater compartment. Based on the current emission characterization there is a potential exposure of metabolites in groundwater exceeding the threshold value of 0.1 µg/L.

The applicant informed that such biodegradability studies will not be provided before the approval date of the active substance and disagreed with the request of additional studies for the three metabolites.

Several BPC members expressed that if no safe use of the active substance can be demonstrated at this stage, the substance cannot be approved with a provision that additional data are submitted after the decision on approval. The BPC members considered therefore that with the current information, a non-approval proposal should be proposed in the BPC opinion.

One member highlighted that the derivation of reference values for human health was not consistent with other isothiazolinones. However, as the AR follows the conclusion of the Human Health Working Group, no changes were made.

The BPC adopted by consensus the opinion for 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 it to the SECR **by 27 January 2017.**
- **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 13 January 2017** and publish it on the ECHA website.

8. Any other business

8.1 Translation of SPC for Union authorisation

The BPC was informed on the procedure developed by ECHA on the "translation of the SPC for Union authorisation applications". Thirty days after the adoption of the BPC opinion ECHA has to submit to the Commission the SPC translated in all official EU languages. This procedure will be discussed at the upcoming Coordination Group meeting.

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 18th meeting of BPC

13-16 December 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 without changes.	**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-17	
The revised version of the minutes of BPC-17 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	
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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 **22 December 2016**. **SECR:** on the basis of the changes to update the WP on the ECHA web site and in the BPC CIRCABC IG. Inform Commission about the status of the submissions for the second priority list.
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	
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7.2 Draft BPC opinion on peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate for PTs 2, 3 and 4	
The BPC adopted by consensus the opinions for the approval of the active substance/PT combinations.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 27 January 2017.**

	SECR: to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinions to COM **by 13 January 2017** and publish it on the ECHA website.
7.3 Draft BPC opinion on active chlorine released from sodium hypochlorite for PTs 1, 2, 3, 4 and 5	
The BPC adopted by consensus the opinions for the approval of the active substance/PT combinations.	**Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 27 January 2017.** **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinions to COM **by 13 January 2017** and publish it on the ECHA website.
7.4 Draft BPC opinion on active chlorine released from calcium hypochlorite for PTs 2, 3, 4 and 5	
The BPC adopted by consensus the opinions for the approval of the active substance/PT combinations.	**Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 27 January 2017.** **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinions to COM **by 13 January 2017** and publish it on the ECHA website.
7.5 Draft BPC opinion on active chlorine released from chlorine for PTs 2 and 5	
The BPC adopted by consensus the opinions for the approval of the active substance/PT combinations.	**Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 27 January 2017.** **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinions to COM **by 13 January 2017** and publish it on the ECHA website.
7.7 Draft BPC opinion on acetamiprid for PT 18	
The BPC agreed to proceed with a written consultation on taking a decision on the selection of reference values for which no agreement was reached at the Human Health Working Group level. Following this written consultation and the inclusion of the outcome of the Public Consultation a written procedure for the adoption	**Rapporteur:** to provide SECR document to launch the written consultation of the BPC on the selection of reference value and its impact on the assessment **by 23 December 2016**. **SECR:** to launch the consultation via S-CIRCABC **by 23 December 2016**. **Members:** to submit comments on the

of the BPC opinion will be launched.	consultation as well as the revised CAR **by 13 January 2017**. **Rapporteur:** in cooperation with the SECR to prepare an amended version of the opinion including the outcome of the written consultation and the Public Consultation. **SECR:** to launch a written procedure for the adoption of the BPC opinion by **27 January 2017**.
7.8 Draft BPC opinion on MIT for PTs 11 and 12	
PT 11: The BPC adopted by consensus the opinion for the approval of this active substance/PT combination. **PT 12:** The BPC agreed to refer the following issues to the Environment Working Group: - the possible reduction of the Assessment Factor for the derivation of the PNEC for the Sewage Treatment Plant; - the use of the monitoring data; - the weight of evidence approach. The outcome of the written consultation will be discussed in a meeting of the Working Group at the end of January 2017.	**PT 11:** **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 27 January 2017.** **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 **13 January 2017** and publish it on the ECHA website. **PT 12:** **Rapporteur:** to provide SECR document to launch the written consultation of the ENV Working Group **by 19 December 2016**. **SECR:** to launch the written consultation of the ENV Working Group **by 19 December 2016**.
7.9 Draft BPC opinion on OIT 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 27 January 2017.** **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 13 January 2017** and publish it on the ECHA website.
7.10 Draft BPC opinion on MBIT for PT 13	
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 discussions in the BPC and submit to the SECR **by 27 January 2017.**

	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 13 January 2017** and publish it on the ECHA website.
Item 8 - AOB	
8.1 Translation of SPC for Union authorisation applications	
The SECR informed the BPC about the procedure for the translation of the SPC for Union authorisation following the adoption of the BPC opinion.	

Part III - List of Attendees

Members	European Commission
BROWN Finbar (IE)	CHATELIN Ludovic (DG SANTE)
CABALLO DIÉGUEZ Covadonga (ES)	**Advisers**
ČEBAŠEK Petra (SI)	CROIZÉ-POURCELET Gilles (FR)
COSTIGAN Michael (UK)	DICKSON Fiona (UK)
DRAGOIU Mihaela-Simona (RO)	GROSSMANN-VEN Stephanie (BE)
GIORDMAINA Wayne (MT)	HADAM Anna (PL)
HADJIGEORGIOU Andreas (CY)	HÄMÄLÄINEN Anna-Maija (FI)
HAHLBECK Edda (SE)	HORSKA Alexandra (SK)
JÄGER Stefanie (DE)	HYVARINEN Tuija (FI)
JOHN Nina (AT)	KARHI Kimmo (FI)
KOIVISTO Sanna (FI)	MOLNAROVA Jana (SK)
LARSEN Jørgen (DK)	PALOMÄKI Jaana (FI)
MERISTE Anu (EE)	PENTTINEN Sari (FI)
MIKOLASKOVA Denisa (SK)	PÜRGY Reinhild (AT)
RUSCONI Manuel (CH)	RITZ Vera (DE)
SZÁNTÓ Emese (HU)	UJMA-CZWAKIEL Monika (PL)
VACEK Tomáš (CZ)	WEINHEIMER Viola (DE)
VRHOVAC FILIPOVIC Ivana (HR)	**Accredited Stakeholder Organisations**
ZOUNOS Athanasios (EL)	COGNAT Flore (CEFIC)
	MONTMOREAU Bertrand (CEPA)
Alternate members	**ECHA Staff**
AZDAD Karima (BE)	AIRAKSINEN Antero
COLLETT Romy (FR)	ESTEVAN MARTINEZ Carmen
CRESTI Raffaella (IT)	JANOSSY Judit
DONS Christian (NO)	LOPEZ SERRANO Paloma
ENSCH Svenja (LU)	NEGULICI Ligia
STAŠKO Jolanta (LV)	NOGUEIRO Eugénia
	PECORINI Chiara
Invited expert	SAEZ RIBAS Monica
HUSZAL Sylwester (PL)	SCHIMMELPFENNIG Heike
	VAN DE PLASSCHE Erik

Applicants	Apologies
DOSOGNE Hilde (Christeyns N.V.) for peracetic acid generated from TAED and sodium percarbonate PT 2, 3, 4	BORGES Teresa (PT)
DZIK Ewa (Dow Polska Sp. z.o.o.) for MBIT PT 13	CAZELLE Elodie (AISE)
KRENN Andreas (Nisso Chemical Europe) for acetamiprid PT 18	KOMEN Corine (NL)
MARINER Richard (Euro Chlor) for active chlorine released from sodium hypochlorite PT 1, 2, 3, 4, 5; active chlorine released from calcium hypochlorite PT 2, 3, 4, 5; active chlorine released from chlorine PT 2, 5	REID Kirsty (Eurogroup for Animals)
SCHOESTER Monika (THOR GmbH) for MIT PT 11, 12	ROSBORG Marianne (EDANA)
TRUISI Germaine (THOR GmbH) for OIT PT 8	
Experts accompanying applicants	
LAO Julien, accompanying KRENN Andreas, for acetamiprid PT 18	
LEUSCH Hans-Josef, accompanying DOSOGNE Hilde, for peracetic acid generated from TAED and sodium percarbonate PT 2, 3, 4	
UEBEL Caroline, accompanying SCHOESTER Monika, for MIT PT 11, 12, and accompanying TRUISI Germaine, for OIT PT 8	
VALLOTTON Nathalie, accompanying DZIK Ewa, for MBIT PT 13	

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-18 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2	BPC-A-18-2016	Draft agenda	
4	BPC-M-17-2016	Draft minutes from BPC-17	
5.2	BPC-18-2016-01	Administrative issues and report from the other Committees	
6.1	BPC-18-2016-02	BPC updated Work Programme 2017-2018	
6.2	BPC-18-2016-03	Outlook for the BPC	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.2	BPC-18-2016-04A	Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate PT 2	Draft BPC opinion
	BPC-18-2016-04B		Assessment report
	BPC-18-2016-04C		Open issues
	BPC-18-2016-05A	Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate PT 3	Draft BPC opinion
	BPC-18-2016-04B		Assessment report
	BPC-18-2016-04C		Open issues
	BPC-18-2016-06A	Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate PT 4	Draft BPC opinion
	BPC-18-2016-04B		Assessment report
	BPC-18-2016-04C		Open issues
7.3	BPC-18-2016-10A	Sodium hypochlorite PT 1	Draft BPC opinion
	BPC-18-2016-10B		Assessment report
	BPC-18-2016-10C		Open issues
	BPC-18-2016-11A	Sodium hypochlorite PT 2	Draft BPC opinion
	BPC-18-2016-11B		Assessment report

	BPC-18-2016-10C		Open issues
	BPC-18-2016-12A	Sodium hypochlorite PT 3	Draft BPC opinion
	BPC-18-2016-12B		Assessment report
	BPC-18-2016-10C		Open issues
	BPC-18-2016-13A	Sodium hypochlorite PT 4	Draft BPC opinion
	BPC-18-2016-13B		Assessment report
	BPC-18-2016-10C		Open issues
	BPC-18-2016-14A	Sodium hypochlorite PT 5	Draft BPC opinion
	BPC-18-2016-14B		Assessment report
	BPC-18-2016-10C		Open issues
7.4	BPC-18-2016-15A	Calcium hypochlorite PT 2	Draft BPC opinion
	BPC-18-2016-15B		Assessment report
	BPC-18-2016-15C		Open issues
	BPC-18-2016-16A	Calcium hypochlorite PT 3	Draft BPC opinion
	BPC-18-2016-16B		Assessment report
	BPC-18-2016-15C		Open issues
	BPC-18-2016-17A	Calcium hypochlorite PT 4	Draft BPC opinion
	BPC-18-2016-17B		Assessment report
	BPC-18-2016-15C		Open issues
	BPC-18-2016-18A	Calcium hypochlorite PT 5	Draft BPC opinion
	BPC-18-2016-18B		Assessment report
	BPC-18-2016-15C		Open issues
7.5	BPC-18-2016-19A	Chlorine PT 2	Draft BPC opinion
	BPC-18-2016-19B		Assessment report
	BPC-18-2016-19C		Open issues
	BPC-18-2016-20A	Chlorine PT 5	Draft BPC opinion
	BPC-18-2016-20B		Assessment report
	BPC-18-2016-19C		Open issues
7.7	BPC-18-2016-22A	Acetamiprid PT 18	Draft BPC opinion
	BPC-18-2016-22B		Assessment report
	BPC-18-2016-22C		Open issues
7.8	BPC-18-2016-23A	MIT PT 11	Draft BPC opinion
	BPC-18-2016-23B		Assessment report
	BPC-18-2016-23C		Open issues
	BPC-18-2016-24A	MIT PT 12	Draft BPC opinion
	BPC-18-2016-24B		Assessment report
	BPC-18-2016-23C		Open issues

7.9	BPC-18-2016-25A	OIT PT 8	Draft BPC opinion
	BPC-18-2016-25B		Assessment report
	BPC-18-2016-25C		Open issues
7.10	BPC-18-2016-26A	MBIT PT 13	Draft BPC opinion
	BPC-18-2016-26B		Assessment report
	BPC-18-2016-26C		Open issues

12 December 2016
BPC-A-18-2016_rev3

Draft agenda

18th meeting of the Biocidal Products Committee (BPC)

13-16 December 2016

ECHA Conference Centre, Annankatu 18, Helsinki

Starts on 13 December at 13:30, ends on 16 December at 12:30

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-18-2016_rev3
For agreement

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

4. – Agreement of the minutes and review of actions from BPC-17

BPC-M-17-2016
For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

BPC-18-2016-01
For information

6. – Work programme for BPC

6.1. BPC Work Programme

BPC-18-2016-02
For information

6.2. Outlook for BPC

BPC-18-2016-03
For information

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. Draft BPC opinion on peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate for PTs 2, 3 and 4

Previous discussion(s): TM-IV-2013; WG-IV-2014; WG-V-2015, WG-IV-2016

PT 2: BPC-18-2016-04A, B and C
PT 3: BPC-18-2016-05A, B and BPC-18-2016-04C
PT 4: BPC-18-2016-06A, B and BPC-18-2016-04C

For adoption

7.3. Draft BPC opinion on sodium hypochlorite for PTs 1, 2, 3, 4 and 5

Previous discussion(s): WG-II-2016, WG-III-2016, WG-IV-2016

PT 1: BPC-18-2016-10A, B and C
PT 2: BPC-18-2016-11A, B and BPC-18-2016-10C
PT 3: BPC-18-2016-12A, B and BPC-18-2016-10C
PT 4: BPC-18-2016-13A, B and BPC-18-2016-10C
PT 5: BPC-18-2016-14A, B and BPC-18-2016-10C

For adoption

7.4. Draft BPC opinion on calcium hypochlorite for PTs 2, 3, 4 and 5

Previous discussion(s): WG-II-2016, WG-III-2016, WG-IV-2016

PT 2: BPC-18-2016-15A, B and C
PT 3: BPC-18-2016-16A, B and BPC-18-2016-15C
PT 4: BPC-18-2016-17A, B and BPC-18-2016-15C
PT 5: BPC-18-2016-18A, B and BPC-18-2016-15C

For adoption

7.5. Draft BPC opinion on chlorine for PTs 2 and 5

Previous discussion(s): WG-II-2016, WG-III-2016, WG-IV-2016

PT 2: BPC-18-2016-19A, B and C

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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).

PT 5: BPC-18-2016-20A, B and BPC-18-2016-19C

For adoption

~~**7.6. Draft BPC opinion on cypermethrin for PT 18**~~

~~*Previous discussion(s): WG-IV-2016*~~

~~BPC-18-2016-21A, B and C~~

~~***For adoption***~~

7.7. Draft BPC opinion on acetamiprid for PT 18

Previous discussion(s): WG-II-2016

BPC-18-2016-22A, B and C

For discussion

7.8. Draft BPC opinion on MIT for PTs 11 and 12

Previous discussion(s): WG-IV-2016

PT 11: BPC-18-2016-23A, B and C

PT 12: BPC-18-2016-24A, B and BPC-18-2016-23C

For adoption

7.9. Draft BPC opinion on OIT for PT 8

Previous discussion(s): WG-IIII-2016

BPC-18-2016-25A, B and C

For adoption

7.10. Draft BPC opinion on MBIT for PT 13

Previous discussion(s): WG-IV-2016

BPC-18-2016-26A, B and C

For adoption

Item 8 – Any other business

8.1. Translation of SPC for Union authorisation applications

For information

Item 9 – Agreement of the action points and conclusions

For agreement

Provisional timeline for the

18th meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Annankatu 18, Helsinki

13 December 2016: starts at 13:30; 16 December 2016: ends at 12:30

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

Tuesday 13 December: afternoon 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	Draft BPC opinion on peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate for PTs 2, 3 and 4

Wednesday 14 December: morning session

Item 7.3	Draft BPC opinion on sodium hypochlorite for PTs 1, 2, 3, 4 and 5
Item 7.4	Draft BPC opinion on calcium hypochlorite for PTs 2, 3, 4 and 5

Wednesday 14 December: afternoon session

Item 7.4	(cont'd) Draft BPC opinion on calcium hypochlorite for PTs 2, 3, 4 and 5
Item 7.5	Draft BPC opinion on chlorine for PTs 2 and 5

Thursday 15 December: morning session

Item 7.7	Draft BPC opinion on acetamiprid for PT 18
Item 7.8	Draft BPC opinion on MIT for PTs 11 and 12

Thursday 15 December: afternoon session

Item 7.9	Draft BPC opinion on OIT for PT 8

Friday 16 December: morning session

Item 7.10	Draft BPC opinion on MBIT for PT 13
Item 8	AOB
Item 9	Agreement of the action points and conclusions

End of meeting