26 February 2019

BPC-M-28-2018

Minutes of the 28th meeting of the Biocidal Products Committee (BPC)

11-14 December 2018

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chairman of the Biocidal Products Committee (BPC) welcomed the participants to the 28th BPC meeting.

Regarding the BPC membership, the Chairman stated that there is a new alternate BPC member for Malta, Lothar Paul Mallia.

The Chairman then informed the BPC members of the participation of 27 members, including 6 alternates.

6 advisers and 1 representative from accredited stakeholder organisations (ASOs) were present at the meeting. One representative from the European Commission attended the meeting.

Applicants were present for their specific substances where 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-28-2018) and invited any additional items. No items were added.

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-27

The revised draft minutes from BPC-27 (BPC-M-27-2018), incorporating the comments received, were agreed.

The Chairman noted that the actions from BPC-27 have been carried out.

The Chairman informed the meeting that the document “Terminology primary and secondary exposure in the BPC opinion” was finalised by the SECR and made available through S-CIRCABC.

The Chairman further informed the meeting that the working procedure for major change applications for Union authorisation is not yet finalised.

The meeting was also informed that a new Article 38 request has been received from the Commission. The draft opinion will be discussed at the Efficacy WG in January followed by a foreseen adoption at BPC-29.

Actions:

- **SECR:** to upload the agreed minutes from BPC-27 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-28-2018-01 prepared by ECHA for the Management Board meeting which contains the progress reports for each Committee including the PBT and ED Expert Groups, and asked the meeting for comments. None were presented.

6. Work Programme for BPC

6.1 BPC Work Programme 2018-2019

6.2 BPC Work Programme 2018-2019 for Union Authorisation

6.3 Outlook for the BPC

The Chairman informed members that the Work Programme was revised after the last BPC meeting and uploaded to BPC CIRCABC IG. A public version was also published on the ECHA website.

The document distributed for this meeting is a revised version following consultations with MSCAs based on information received following the dissemination of the previous version. Members were invited to contact the SECR on possible changes by 4 January 2019 after which an updated version will be published on the ECHA website.

The Chairman stated that:

- For active substance approval the number of opinions adopted this year is 25 of which 18 are returned for an ED assessment under Article 75(1)(g). In addition, if all opinions scheduled for this meeting are agreed, in total 38 opinions have been agreed or adopted in 2018 which is 4 more than in 2017.
- The current ECHA work programme document for active substance approval is no longer realistic as almost all dossiers are scheduled for a certain process flow but are moved to the next one by the next BPC meeting: so all dossiers which were

scheduled for process flow 31 are now moved to 32. In other words, no draft evaluations are submitted for peer review by the eCAs already for some time in spite of what is indicated in the ECHA work programme document. The Chairman indicated that this makes it difficult for the SECR to plan meetings in 2019 and asked the members to improve their planning capabilities.

- For Union authorisation the number of adopted opinions for 2018 is will be 4. The Chairman refered to agenda item 8.1 for a further discussion. The Chairman invited the members to comment on the work programme for Union authorisation.

The Chairman asked the eCAs with active substances scheduled for discussion at the February 2019 BPC meeting (BPC-29) to confirm this planning to the SECR by 15 January 2019.

Similarly to previous meetings, the Commission expressed concerns on the general progress and reminded that Member States must implement the actions agreed at the CA meeting, in particular to deliver the draft assessment reports, and to not postpone discussions on their substances from BPC meetings to BPC meetings. Progress must also be made on backlog reports submitted before 1 September 2013.

SECR presented a short overview on the 'Grip on the Review Programme' project. SECR will prepare a final report on the project including the indentified findings and progress on the Review Programme. This report will be the basis for a workshop on the active substance approval process to take place in ECHA on 12-13 February 2019. MSCAs have been asked to nominate representatives, including middle manager and coordinator as well as BPC or WG members. SECR reminded the meeting of the possibility of assistance from ECHA to eCAs in case the evaluation on specific substances is not progressing. For this SECR asked the MSs to proactively contact ECHA if support in evaluation work is considered. SECR informed the meeting about the development of the interact portal.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) for active substance approval and Union authorisation to the SECR by **4 January 2019**.
- **SECR**: on the basis of the changes to update the work programme on the ECHA website and in the BPC CIRCABC IG.
- **The relevant eCAs** to confirm to the SECR that their active substances scheduled for discussion at February BPC meeting will remain on track by **15 January 2019**.

6.4 Status harmonised classification and labelling for active substances

The SECR presented a revised overview on the status of harmonised classification and labelling of active substances which have been approved or are still under review. The table is based on the tracking table of the Coordination Group and will be updated for each BPC. The Commission reminded members that it is important that Member States prepare CLH dossiers for harmonised classification as required under the CLP regulation so that all active substances have an up-to-date harmonised classification. This is in particular important when active substances meet the exclusion or substitution criteria due to their classification as previously agreed by Competent Authorities. The Chairman informed the meeting that ECHA will inform the Biocides CA meeting and CARACAL of this overview.

Actions:

- **Members:** to provide comments on the overview by **25 January 2019**.

6.5 Status ED assessment for active substances

The SECR presented an overview on the status of the ED assessment of active substances. The overview shows the progress on ED assessments following Article 75(1)(g) request from COM as well as the progress of substances with agreed but not adopted BPC opinions, due to missing ED assessment and which have been returned to the eCA.

The Commission thanked for the overview and requested that ECHA's tracking is extended to all active substances still under examination to ensure a good monitoring and coordination on this topic.

Actions:

- **Members:** to provide comments on the overview by **25 January 2019**.

7. Applications for approval of active substances

7.1.1 Template BPC opinion for active substance approval

The Chairman mentioned that the template has been modified with respect to the title of section 2.2.3. Comments were received from the Commission which were distributed to the BPC. The meeting agreed on the revised title: “Identification of potential alternative substances or technologies, including the results of the public consultation for potential candidates for substitution". The meeting discussed to some extent the requirements related to the identification of alternatives under the approval process. The Commission reminded the importance of the BPC role in the identification of potential alternatives to active substances subject to exclusion/substitution.

Actions:

- **SECR:** to upload the revised template on the BPC CIRCABC IG and to consult with the Commission on improving the process on the identification of possible alternatives for potential candidates for substitution.

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

The Chairman stated that this document has not been changed compared to the previous versions. It is listed for information and members preparing BPC opinions are asked to make use of the standard phrases.

7.1.3 Presentation of PBT status in BPC opinion: potential PBTs

The document prepared by the SECR was agreed. No comments were made.

Actions:

- **SECR:** to upload the document on the BPC CIRCABC IG.

7.2 Draft BPC opinion on silver zinc zeolite for PT 2, 7 and 9

The Chairman welcomed the applicant for this item and introduced the agenda item. The applicant did not object to the presence of the ASOs during the discussion. The rapporteur introduced the amended draft opinions and explained two newly introduced conditions in section 2.3 compared to the initial discussions at BPC-27. The amended draft opinions were used as the basis for the discussion including the open issue tables prepared for the BPC-28 meeting and remaining open issues from the tables prepared for the BPC-27 meeting.

Product Type 2

Section 2.1.b: on target organisms and effectiveness a member commented to use the term 'prevents human infection' instead of 'prevents cross contamination' (comment 17; BPC-28[1]). The rapporteur disagreed, claiming that the requested change would result in a medical claim and that only an antimicrobial effect can be demonstrated, which is anyway a claim made by the applicant (in this case, an antimicrobial effect has not been demonstrated, however, but only a bacteriostatic effect). It was discussed that in principle claims made by an applicant should not be altered, only commented on. It was agreed to add an explanatory footnote for 'cross contamination'.

Section 2.1.b: a member asked for a definition of the term 'dry surrounding' and suggested to apply a humidity threshold of 60% (comment 18; BPC-28). It was agreed to add information on what is understood by the term dry surroundings in the Assessment Report. Another member asked for a definition of 'wet conditions'. The applicant explained that the products were not meant to release silver under dry conditions, while e.g. a hand print would be sufficiently wet to release silver. It was concluded that there is no need to include definitions on dry or wet conditions in the opinions as the conditions proposed for approval in section 2.3 do not refer to these terms.

Section 2.1.c (human health): it was agreed to not include the percentage of the active substance of the formulation for the mixing and loading (comment 2; BPC-28).

Section 2.1.c (human health): it was discussed if both the assessments for product A and product B need to be included in the opinion (comment 86; BPC-27). The applicant reminded the BPC that product A was based on a maximum concentration and worst-case application rates. It was agreed to describe in the opinions that more products were assessed, products which differ in concentration of the active substance and in migration rates from the final polymer due to the composition of the biocidal product. However, only the , result of the 'worst case assessment' will be included in the opinion.

[1] This and the following comments refer to comments from the open issue table prepared for either BPC-27 or BPC-28.

Section 2.1.c (human health): it was concluded to amend the title of the table *'Use in paints and coatings*' to "Use of liquid biocidal products (paints and coatings)" (comment 87; BPC-27).

Section 2.1.c (human health): the footnote in the table "non-textile polymers" explaining an "exposure category" was discussed (comment 4; BPC-28). At the BPC-27 meeting, it was decided to remove the examples and after some discussion this decision was re-confirmed. More explanation will be given in the Assessment Report – with examples – on this, including the terms small, medium and large scale. It was concluded to remove the reference to scales in the footnote but leave the use of the term "scales" in the tables. One of the issues considered was that it is difficult to list examples as often it is unknown if these belong to the Product-Type under consideration. Another issue considered was that one will connect the term "scale" to surface area while it is a combination of exposure duration and surface. It was concluded that this may need to be reconsideredif restrictions are to be included for treated articles.

Section 2.1.c (human health): in the table "Textile polymers" it was decided to remove the scenario "Textiles not intended for direct skin contact" in line with previous opinions (comment 19; BPC-28).

Section 2.1.c (environment): following a question from one of the members it was clarified that no assessment was carried out for indoor use of paints and coatings (which includes sealants) as it is assumed that there will be no emission to the environment for indoor use. It was therefore decided to remove these from the opinion (comment 6; BPC-28).

Section 2.1.c (overall conclusion): it was decided that – as an approval is proposed – the safe use(s) identified need to be clearly described in this section (comment 8; BPC-28). Several other issues were discussed on the "Overall conclusion": to remove the word "exclusively" in the sentence '*SZZ is exclusively used to treat articles'* as this is not correct (comment 64; BPC-27); provide an explanation why unacceptable risks cannot be mitigated for some scenarios (comment 8; BPC-28); if restrictions are included in section 2.3, describe the major concern identified which motivates the restrictions as indicated in the relevant CA document. It was mentioned by some members that although an unacceptable risk is identified it is possible that the risk assessment could be refined by the introduction of additional data or additional mitigation measures.

Section 2.3 (conditions for placing on the market of treated articles): the restrictions proposed due to a lack of efficacy for some uses and / or target organisms, were supported by some members (comments 9 -11; BPC-28). However, the majority of the members suggested to remove these restrictions as innate efficacy has been demonstrated and more information can be submitted during product authorisation. Doubts were also expressed on the enforceability of the proposals, for example related to the reference to "articles intended to be used in dry surroundings" where a clear definition for enforcers would be needed for the term "dry surroundings". The Chairman concluded to remove these proposals.

Section 2.3 (conditions for placing on the market of treated articles): different opinions were expressed on the proposal to include restrictions related to the unacceptable risks identified (comments 12 – 15; BPC-28). Some members re-iterated that there is a major concern, as unacceptable risks have been identified, and that this concerns also vulnerable groups. Other members did not support the proposals as there is still the possibility to refine the assessment by the introduction of additional data or additional mitigation measures. at product authorisation. The rapporteur emphasised that when it comes to

restrictions on treated articles, the path foreseen by the legislator to refine the assessment is not via product authorisation but via an Art. 7 application for amendments of the conditions of approval. Other members did not support the proposals as these were not considered consistent with other opinions or that they doubted if these conditions are enforceable. Following a vote, the Chairman concluded that the BPC supported the proposals.

Subsequently, the phrasing of the proposed conditions was discussed. It was argued by the Commission that the BPC needs to be consistent and that, if the BPC proposes restrictions on treated articles, it needs also to propose restrictions on the authorisation of biocidal products which would serve to make the concerned treated articles. Not all members considered this necessary.

Section 2.3 (conditions on the placing of the market of treated articles): with respect to three other conditions proposed it was concluded to remove two conditions ("The person responsible for the placing on the market of an article treated with or incorporating silver zinc zeolite shall ensure that the label of that treated article makes clear which uses are permitted." and "The person responsible for the placing on the market of an article treated with or incorporating silver zinc zeolite shall ensure that the label of that treated article makes clear that the article is not used in situations where it can be expected to come into contact with food.") and keep the general standard condition ("The person responsible for the placing on the market of a treated article treated with or incorporating the active substance silver zinc zeolite shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012").

Product Type 7 and 9

Several of the comments discussed under PT 2 were also considered relevant under PT 7 and 9 (for example on the section on the "Overall conclusion"). With respect to section 2.3.3 similar decisions were taken by the members concerning the proposed conditions on the placing on the market of treated articles. With respect to proposed conditions related to indentified unacceptable risks for the environment, it was decided to not include such conditions as the members considered that no major concern was identified. Subsequently, the phrasing of the proposed conditions was discussed.

Overall, it was concluded that SECR and the Rapporteur will re-draft the proposed conditions in line with the discussions of the BPC.

Actions:

- **Rapporteur and SECR:** to revise the draft opinions by **31 January 2019** and initiate a written consultation on the revised draft opinions.
- **Rapporteur:** to perform the ED assessment and return the opinions and Assessment Reports to ECHA.

7.3 Draft BPC opinion on silver zeolite for PT 9

Several of the comments discussed under silver zinc zeolite PT 2 were also considered relevant for silver zeolite for PT 9 (for example on the section on the "Overall conclusion"). With respect to section 2.3 similar decisions were taken by the members concerning the proposed conditions on the placing on the market of treated articles. With respect to

proposed conditions related to indentified unacceptable risks for the environment it was decided to not incude such conditions as the members did consider that therequirement of the identification of a major concern was not met. Subsequently, the phrasing of the proposed conditions was discussed.

Actions:

- **Rapporteur and SECR:** to revise the draft opinions by **31 January 2019** and initiate a written consultation on the revised draft opinions.
- **Rapporteur:** to perform the ED assessment and return the opinions and Assessment Reports to ECHA.

7.4 Draft BPC opinion on silver copper zeolite for PT 9

Several of the comments discussed under silver zinc zeolite PT 2 were also considered relevant for silver copper zeolite for PT 9 (for example on the section on the “Overall conclusion”). With respect to section 2.3.3 similar decisions were taken by the members concerning the proposed conditions on the placing on the market of treated articles. With respect to proposed conditions related to indentified unacceptable risks for the environment it was decided to not incude such conditions as the members did consider that the requirement of the identification of a major concern was not met.Subsequently, the phrasing of the proposed conditions was discussed.

Actions:

- **Rapporteur and SECR:** to revise the draft opinions by **31 January 2019** and initiate a written consultation on the revised draft opinions.
- **Rapporteur:** to perform the ED assessment and return the opinions and Assessment Reports to ECHA.

7.5 Draft BPC opinion on silver sodium hydrogen zirconium phosphate for PT 9

Several of the comments discussed under silver zinc zeolite PT 2 were also considered relevant for silver sodium hydrogen zirconium phosphate for PT 9 (for example on the section on the “Overall conclusion”). With respect to section 2.3.3 similar decisions were taken by the members concerning the proposed conditions on the placing on the market of treated articles. With respect to proposed conditions related to indentified unacceptable risks for the environment it was decided to not incude such conditions as the members did consider that the requirement of the identification of a major concern was not met. . Subsequently, the phrasing of the proposed conditions was discussed.

Actions:

- **Rapporteur and SECR:** to revise the draft opinions by **31 January 2019** and initiate a written consultation on the revised draft opinions.
- **Rapporteur:** to perform the ED assessment and return the opinions and Assessment Reports to ECHA.

7.6 Draft BPC opinion on ADBAC and DDAC for PT 3 and 4

The Chairman welcomed the applicant for this item and introduced the agenda items. The applicant did not object to the presence of the ASOs during the discussion. The rapporteur pointed out that the assessment of the endocrine disruptor properties was not finalised and the BPC opinion cannot be adopted at the meeting. The discussion focussed on the items included in the open issues table regarding the comments on the AR and the draft BPC opinion. The Chairman invited the BPC members to agree on the comments of the ARs and opinions and noted that similar comments were made by the members and the applicants for both DDAC and ADBAC.

Regarding the request for the submission of additional validation data regarding the analysis of specific residues in various matrices of animal origin, the rapporteur explained this is the outcome of the APCP WG discussions. The Chairman confirmed the view of the rapporteur. The applicant pointed out that another method was used to establish the temporary MRL value for BAC and DDAC as laid down in Regulation (EU) No 1119/2014. Consequently, the applicant questioned if another method will used for the re-evaluation of the temporary MRL. It was concluded that ECHA will consult with EFSA on this issue.

The applicant raised objections to the use of two open literature studies that were introduced during the peer review and used for the derivation of the LOAEC for the respiratory tract. The rapporteur clarified that this was agreed in an ad-hoc follow-up by the Human Health Working Group. The applicant stated that they object “to the use of such studies of an unknown quality and un-proven substance identification being used for such a critical regulatory endpoint setting”.

An extensive ad hoc follow-up took place after the first discussion in the WG Environment with several discussion rounds. The rapporteur indicated that the environmental risk assessment as described in the draft CAR for this meeting contains some mistakes but that the conclusions as indicated in the draft BPC opinion are still valid. This was confirmed by the SECR. One member stated that there was insufficient time to peer review the latest version of the environmental risk assessment and therefore could not agree with the conclusions laid down in the BPC opinion. It was decided that the revised assessment to be prepared by the rapporteur after the meeting will be forwarded to this BPC member for agreement via a written consultation.

The paragraph about the potential development of resistance was discussed and more specifically the consistency with other opinions. A BPC member proposed to delete the statement about the static activity as this was not claimed by the applicant. However, the BPC member indicated that there is some known potential of resistance already described for quartenary ammonium compounds in the literature. It was proposed to align the wording in the opinion with other opinions, for example the one for CMIT/MIT. Following a remark from the Commission, the Chairman clarified that how to assess information on resistance and management of resistance is taken on board by the EFF WG.

One member was concerned about the food risk assessment which will need to be performed after the approval of the active substance under product authorisation. The reason was that since a guidance for dietary risk assessment is still not ready, this aspect for PT4 is postponed to product authorization. Furthermore, there is no guidance and/or a harmonized approach on how to perform this assessment for active substances with local effects for which no ADI or ARfD is derived. The Chairman pointed out the need for further discussion and confirmed that this will be put forward to the Human Health WG. For PT3, one member commented that according to a preliminary dietary risk assessment (DRA)

performed by the eCA acceptable risks were identified considering an efficient rinsing step. This member suggested to clarify this conclusion in the opinion, and to add a provision related to the efficiency of rinsing step to be demonstrated at product authorization stage, in line with the approach followed previously in the opinion of PHMB PT3. It was concluded that ECHA would check whether the situation of ADBAC and BKC is comparable to PHMB as regard to the DRA and harmonize the opinions if relevant.

The rest of the issues, indicated in the open issues table were discussed and agreed by the Committee.

The Commission remarked that it is indicated in section 2.5 of the draft opinion that some data are still missing after 10 years of examination, reminded that all data should normally be provided at the submission of applications, and strongly invited the applicant to provide the missing data before the BPC opinion is finalised as the ED assessment is still on-going. As ADBAC/DDAC has not been the sole active substance in this situation, the Commission re-iterated its request to Member States to be more vigilent on this aspect, to identify and request missing information at the early stages of assessment.

Actions:

- **Rapporteur:** to perform the ED assessment and return the opinions and Assessment Reports to ECHA.

7.7 Draft BPC opinion on icaridin for PT 19

The Chairman welcomed the applicant. The ASOs were allowed to be present during the discussion. The rapporteur introduced the substance and clarified that the assessment has been submitted before 1 September 2013 in accordance with the BPD requirements. Furthermore, the rapporteur pointed out that the assessment of the endocrine disruptor properties was not finalised and the BPC opinion cannot be adopted at the meeting. The discussion focussed on the items included in the open issues table regarding the comments on the AR and the draft BPC opinion.

In particular, the members discussed the assessment factor used for the derivation of the Acceptable Exposure Level (AEL). Following a request from the BPC made at an earlier meeting, the Commission clarified that for active substances for which the assessment is submitted before 1 September 2013 in accordance with the BPD, historical human data (which are available for icaridin) can be used to lower the safety factor for the risk assessment. For active substances for which the assessment is submitted after 1 September 2013 in accordance with the BPR, this is not possible due to the provisions in section 1.1.3 of Annex IV. When it comes to the product authorisation stage for icaridin the Commission will clarify whether the same safety factor and/or AEL can be used. The applicant pointed out that using a different AEL value for icaridin for active substance approval and product authorisation is unprecedented and should not be the practice.

Regarding the reference to the product name and the specific doses the members agreed that these should be removed from the BPC opinion.

As regard to efficacy, it was decided to delete the restriction set in 2.3 of the opinion related to the demonstration of efficacy against target organism *Culex quinquefasciatus* only. Efficacy will be assessed at product authorization stage against the target organisms claimed by the applicants.

The Commission pointed out that there should be consistency between the human health and the environmental risk assessment, since the environmental calculation was carried out only for one application per day and the human health for two applications per day. It was agreed that the reason behind this needs to be clarified and to state the safe use identified in the overall conclusion.

With regards to the risk identified for children younger than 2 years, it was clarified by the applicant that the risk assessment took into account the ingestion of the active substance from the whole hand without the bittering agent. After thorough discussion on this point, the Committee agreed that no restriction was needed with regard to children younger than 2 years in the BPC opinion as some refinement could be possible, however it should be stated that particular attention should be paid at product authorisation stage since an unacceptable risk has been identified.

In addition to the open issues, the applicant asked to mention in the AR the fact that the study to demonstrate the kidney effects was offered several times and at the time of the discussions it was not considered relevant. The applicant highlighted that the rate of the AEL, as set, would not allow for future applicants to demonstrate a safe use. In relation to this point, the Chairman clarified that a refinement of the AEL would be possible depending on the tests performed for the product authorisation stage. If needed, after peer review a list of endpoints may be refined.

The Commission remarked that it is indicated in section 2.5 of the draft opinion that some data are still missing after 10 years of examination, reminded that all data should normally be provided at the submission of applications, and strongly invited the applicant to provide the missing data before the BPC opinion is finalised as the ED assessment is still on-going. The Commission re-iterated its request to Member States to be more vigilent on this aspect, to identify and request missing information at the early stages of assessment.

The rest of the issues, indicated in the open issues table were discussed and agreed by the Committee. The Assessment Report and the BPC opinion were agreed, with the exception of the ED assessment against the new criteria.

Actions:

- **Rapporteur:** to perform the ED assessment and return the opinion and Assessment Report to ECHA.

7.8 Revised Assessment Report following the submission of data after active substance approval

7.8.1 Peracetic acid for PT 1- 6, 11 and 12

The involved evaluating CA Finland informed the meeting that they accepted the post approval data submitted by the applicant. This was agreed by the meeting.

Actions:

- **Member (FI):** to forward the revised assessment report with the List of Endpoints to the SECR by **25 January 2019**.

7.8.2 Tralopyril for PT 21

The involved eCA (UK) informed the meeting that they accepted the post approval data submitted by the applicant. The following issues were discussed:

Confirmatory data on the reference source. The eCA reported that the original reference source had ceased manufacture of the active substance. Technical equivalence was confirmed by two alternative sources in the meantime. Therefore eligible sources of the active substance are available for product authorisations. The BPC agreed that this can be accepted because the provided information did not lead to a change of the reference specification and because eligible sources are available.

Analytical methods for monitoring in air. The analytical methods for monitoring in air must be sensitive enough to cover the lowest AEL (in this case for long term exposure). However, the provided methods cover only the higher inhalatory AEL. The eCA explained that possibly unclear advice was given to the applicant about the required sensitivity of the methods. It was agreed that the analytical methods for monitoring in air can be accepted at this stage of the active substance approval process in view of this circumstance. Sufficient sensitivity of the method must be demonstrated at the renewal of the active substance.

Analytical methods for monitoring in shell fish and fish tissue. The analytical methods for monitoring in shell fish and fish tissue must demonstrate recovery with five measurements. The methods provided measured only three times the recovery. It was agreed that the analytical methods can be accepted at this stage of the active substance approval process despite the fact that the recovery was measured only three times. Acceptable methods with the required five measurements of recovery must be provided at renewal stage of the active substance.

Overall, the Commission regretted that even more than 3 years after the approval of this substance, some acceptable data has still been missing, and that the issues are not totally solved. It pointed out that this illustrates its earlier comment that there should no longer be missing data on active substances when the BPC concludes its review. Actions must be taken by evaluating CAs in this respect to improve this situation.

Actions:

- **Member (UK):** to forward the revised assessment report with the List of Endpoints to the SECR by **25 January 2019**.

7.8.3 S-methoprene for PT 18

The involved evaluating CA Ireland informed the meeting that they accepted the post approval data submitted by the applicant and that the data have been reviewed by the Environment Working Group. This was agreed by the meeting.

Actions:

- **Member (IE):** to forward the revised assessment report with the List of Endpoints to the SECR by **25 January 2019**.

7.9 Requesting further information as new test guidelines become available

The Chairman stated that no revised document was prepared as only few members submitted information on whether they have similar cases like the ones described in the document. Subsequently, the SECR did withdraw the document and decide on a case-by-case basis rather than providing a generic 'solution' for the issue of in-vivo site of contact mutagenicity testing. The Chairman invited eCAs to contact ECHA, if needed, for advice on their individual dossier.

7.10 Systematic literature review for ED assessment

The SECR proposal – laid down in the document prepared for the meeting - was that for the backlog dossiers for which the applicant is not willing to perform a systematic literature review for the ED assessment, this would be done by the eCA but only in the case that there are already indications that the active substance might have ED properties. Some members considered that it would not be appropriate to put the responsibility of the literature review to the eCA, as it would require a lot of work and reaching a conclusion would in any case be unlikely as no new information can be requested. Other members considered it necessary to perform a systematic literature review in all cases to ensure that the available relevant information is taken into account. One member suggested to check which substances are still in the backlog for which the evaluation of additional PTs would still be on-going. This would help identifying the cases for which a full ED assessment is in any case going to be performed in the context of these other PTs. This analysis should also include those active substances for which the Commission returned the already adopted BPC opinion (under Article 75(1)(g)) because of the ED assessment. It was highlighted that the MSCAs would have to be mindful of agreeing on the possibility of not performing a systematic literature review, as in such a case, the CAs should in consistency also agree to vote in favour of the approval of such substances for which this review was not performed and for which no conclusion on the ED properties could thus be made. One member asked that ECHA makes the literature search instead of the eCA.

The majority of the members were in favour of the principles proposed in the document. The SECR will provide a revised version for agreement.

7.11 Biocides assessment and RAC opinion on harmonised classification (CLH)

The SECR presented the document. One member asked to add that the WGs should also discuss classification in relation to the exclusion and substitution criteria (e.g. is available information sufficient for decision). This member did also not agree with the SECR document, noting that the CA meeting document "CA-Nov14-Doc.4.5–Final" informs that if exclusion criteria are proposed to be met, it would be necessary that the RAC opinion is available before the peer review on the draft CAR is initiated. This is to avoid a non-approval of a substance based on a CLH proposal which later on might not be confirmed by RAC. Similarly, properties like mutagenicity may trigger a very conservative risk assessment which could have severe consequences comparable to the exclusion criteria, and therefore a RAC opinion should maybe be available also for these substances before a BPC opinion is adopted. SECR pointed out that this would not solve the issue for a case

where no harmonised classification and labelling (CLH) would be warranted due to the information being insufficient, inconclusive or unreliable. For such cases, there is a probability that the conclusion of the BPC might differ from the RAC, as the decision of the RAC not to classify for a certain hazard property does not necessarily mean in reality the absence of that hazard property. The members wanted to have clarity on the proposal a) presented in the document.

Actions:

- **Members:** to provide comments on the document by **25 January 2019**.

8. Union authorisation

8.1 Update on Union authorisation

An update on Union authorisation was given by the SECR to present: an overview of the current status of the applications in the ECHA's pipeline; an outline of the ongoing activities; some proposals for improving the Union authorisation process at different procedural stages; and the planning for the discussions at the upcoming Working Group and BPC meetings.

Actions:

- **SECR:** to upload the presentation to S-CIRCABC.

8.2 Draft BPC opinion on Union authorisation application for a product family containing iodine / PVP-iodine

The Chairman noted that the applicant was not represented at the meeting. The ASOs were allowed to be present during the discussion. The discussion focussed on the items included in the open issues table.

With regard to the combined uses (pre- and post-milking uses) in meta SPC 2 and 3, an additional precautionary statement was agreed to be added in order to prevent additional application with other iodine containing products. The following sentence will be added under Section 4. Use-specific risk mitigation measures: "This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product." In addition, SECR pointed out that the risk mitigation measures, regarding the personal protective equipment for the different uses, should be aligned between the PAR and SPC. Proposals presented by the SECR were discussed and agreed upon.

All items in the open issues table were addressed. The BPC opinion, the draft SPC and the PAR will be revised according to the conclusions taken at the BPC and as reflected in the open issue table. The BPC opinion, the PAR and the draft SPC were adopted by consensus.

Actions:

- **Rapporteur**: to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **20 December 2018.**

- **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, draft SPC and PAR to COM by **21 December 2018**.
- **SECR**: to forward the translated draft SPC to COM by **21 January 2019.**

9. Any Other Business

-

10. 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 28th meeting of BPC

11-14 December 2018

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-27	
The revised version of the minutes of BPC-27 was agreed as proposed.	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website.
Item 5 – Administrative issues	
-	**-**
Item 6 - Work programme for BPC	
6.1 BPC Work Programme 2018-2019 for active substance approval **6.2 BPC Work Programme 2018-2019 for Union authorisation**	
-	**Members:** to send information on any further changes to the Work Programme (WP) to the SECR by **4 January 2019.**
6.3 Outlook for BPC	
-	-
6.4 Status harmonised classification and labelling for active substances	
-	**Members:** to provide comments on the overview by **25 January 2019**.
6.5. Status ED assessment for active substances	
-	**Members:** to provide comments on the overview by **25 January 2019**.

Item 7 - Applications for approval of active substances	
7.1. Procedural and administrative aspects	
7.1.1 Template BPC opinion for active substance approval	
The BPC agreed the revised BPC opinion template.	**SECR:** to upload the revised template on the BPC CIRCABC IG and to consult with the Commission on improving the process on the identification of possible alternatives for potential candidates for substitution.
7.1.2 Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval	
-	-
7.1.3 Presentation of PBT status in BPC opinion: potential PBTs	
The BPC agreed on the document.	**SECR:** to upload the document on the BPC CIRCABC IG.
7.2 Draft BPC opinion on silver zinc zeolite for PT 2, 7 and 9	
The BPC agreed on the draft opinions and Assessment Reports for the approval of the active substance/PT combinations. However, as the draft opinions did not contain an assessment of the ED criteria the opinions could not be adopted.	**Rapporteur and SECR:** to revise the draft opinions by **31 January 2019** and initiate a written consultation on the revised draft opinions. **Rapporteur:** to perform the ED assessment and return the opinions and Assessment Reports to ECHA.
7.3 Draft BPC opinion on silver zeolite for PT 9	
The BPC agreed on the draft opinion and Assessment Report for the approval of the active substance/PT combination. However, as the draft opinion did not contain an assessment of the ED criteria the opinion could not be adopted.	**Rapporteur and SECR:** to revise the draft opinion by **31 January 2019** and initiate a written consultation on the revised draft opinion. **Rapporteur:** to perform the ED assessment and return the opinion and Assessment Report to ECHA.
7.4 Draft BPC opinion on silver copper zeolite for PT 9	
The BPC agreed on the draft opinion and Assessment Report for the approval of the active substance/PT combination. However, as the draft opinion did not contain an assessment of the ED criteria the opinion could not be adopted.	**Rapporteur and SECR:** to revise the draft opinion by **31 January 2019** and initiate a written consultation on the revised draft opinion. **Rapporteur:** to perform the ED assessment and return the opinion and Assessment Report to ECHA.
7.5 Draft BPC opinion on silver sodium hydrogen zirconium phosphate for PT 9	
The BPC agreed on the draft opinion and Assessment Report for the approval of the active substance/PT combination. However, as the draft	**Rapporteur and SECR:** to revise the draft opinion by **31 January 2019** and initiate a written consultation on the revised draft opinion.

opinion did not contain an assessment of the ED criteria the opinion could not be adopted.	**Rapporteur:** to perform the ED assessment and return the opinion and Assessment Report to ECHA.
7.6 Draft BPC opinion on ADBAC and DDAC for PT 3 and 4	
The BPC agreed on the draft opinions and Assessment Reports for the approval of the active substance/PT combination. However, as the draft opinions did not contain an assessment of the ED criteria the opinions could not be adopted.	**Rapporteur:** to perform the ED assessment and return the opinions and Assessment Reports to ECHA.
7.7. Draft BPC opinion on icaridin for PT 19	
The BPC agreed on the draft opinion and Assessment Report for the approval of the active substance/PT combination. However, as the draft opinion did not contain an assessment of the ED criteria the opinion could not be adopted.	**Rapporteur:** to perform the ED assessment and return the opinion and Assessment Report to ECHA.
7.8 Revised Assessment Report following the submission of data after active substance approval	
7.8.1 Peracetic acid for PT 1- 6, 11 and 12	
The member from FI informed the BPC about the evaluation of the data submitted after the approval.	**Member (FI):** to forward the revised assessment report with the List of Endpoints to the SECR by **25 January 2019.**
7.8.2. Tralopyril for PT 21	
The member from UK informed the BPC about the evaluation of the data submitted after the approval.	**Member (UK):** to forward the revised assessment report with the List of Endpoints to the SECR by **25 January 2019.**
7.8.3. S-methoprene for PT 18	
The member from IE informed the BPC about the evaluation of the data submitted after the approval.	**Member (IE):** to forward the revised assessment report with the List of Endpoints to the SECR by **25 January 2019.**
7.9 Requesting further information as new test guidelines become available	
The document was withdrawn by the SECR. It was agreed that in case of a possible request for further information as a new test guideline has become available this needs to be decided on a case-by-case basis.	
7.10 Systematic literature review for ED assessment	
The BPC discussed the document on systematic literature review for ED assessment.	
7.11 Biocides assessment and RAC opinion on harmonised classification (CLH)	
The BPC discussed the document on the biocides assessment and RAC opinion on harmonised classification (CLH).	**Members:** to provide comments on the document by **25 January 2019**.

Item 8 – Union authorisation	
8.1 Update on Union authorisation	
The meeting was informed about the developments on Union authorisation.	**SECR:** to upload the presentation on the BPC CIRCABC IG.
8.2 Draft BPC opinions on Union authorisation applications for a product family containing iodine / PVP-iodine	
The BPC adopted by consensus the opinion for the authorisation of the application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **20 December 2018**. **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, draft SPC and final PAR to COM by **21 December 2018**. **SECR**: to forward the translated draft SPC to COM by **21 January 2019**.
Item 9 – Any other business	
-	-

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Part III - List of Attendees

Members	European Commission
BORGES Teresa (PT)	CHATELIN Ludovic (DG SANTE)
BROVKINA Julija (LV)	
CEBASEK Petra (SI)	
COSTIGAN Michael (UK)	**Advisers**
DRAGOIU Simona (RO)	BALDASSARRI Lucilla (IT)
GAVRIEL Alexandros (CY)	FRANK Ulrike (SE)
GONZALEZ MARQUEZ Maria Luisa (ES)	HÄMÄLÄINEN Anna-Maija (FI)
GREGERSEN Nina Falk (DK)	KARHI Kimmo (FI)
HADAM Anna (PL)	CORDUA Birgitte Skou (DK)
HAHLBECK Edda (SE)	WEINHEIMER Viola (DE)
JAGER Stefanie (DE)	
KOIVISTO Sanna (FI)	
LANS Martine (NL)	**Accredited Stakeholder Observers**
MERISTE Anu (EE)	MIHAI Camelia (CEFIC)
MIKOLASKOVA Denisa (SK)	
RANDALL Marit (NO)	
SZANTO Emese (HU)	**ECHA Staff**
VACEK Tomas (CZ)	AIRAKSINEN Antero
VAGIAS Vasileios (EL)	ESTEVAN MARTINEZ Carmen
VRHOVAC FILIPOVIC Ivana (HR)	GUTIERREZ ALONSO Simon
ZIGRAND Jeff (LU)	JANKA Adel
	KURONEN Terhi
Alternate members	LOPEZ SERRANO Paloma
AZDAD Karima (BE)	MATTHES Jochen
CARBERRY Stephen (IE)	MULLER Gesine
COLLET Romy (FR)	SCHIMMERLPFENNIG Heike
CRESTI Raffaella (IT)	VAN DE PLASSCHE Erik
MALLIA Lothar Paul (MT)	VAN DER LINDEN Sander
PYTHON Francois (CH)	VAN GALEN Joost

Applicants	Apologies
AkzoNobel Surface Chemistry AB and as representing EQC	JOHN Nina (AT)
EU BPR Silver Task Force	
Janssen PMP	
Lonza Ltd	
Saltigo GmbH	

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-28

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-28 meeting

Meeting documents		
Agenda Point	**Number**	**Title**
2	BPC-A-28-2018	Draft agenda
4	BPC-M-27-2018	Draft minutes from BPC-27
5.2	BPC-28-2018-01	Administrative issues and report from the other Committees
6.1	BPC-28-2018-02	BPC Work Programme 2018-2019
6.2	BPC-28-2018-03	BPC Work Programme 2018-2019 for Union Authorisation
6.3	BPC-28-2018-04	Outlook for the BPC
6.4	BPC-28-2018-05	Status harmonised classification and labelling for active substances
	BPC-28-2018-05_Rev_Room doc_1	
6.5	BPC-28-2018-06	Status ED assessment for active substances
7.1	Procedural and administrative aspects:	
	BPC-28-2018-07	7.1.1. Template BPC opinion for active substance approval
	BPC-28-2018-08	7.1.2. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval
	BPC-28-2018-09	7.1.3. Presentation of PBT status in BPC opinion: potential PBTs
7.8	Revised Assessment Report following the submission of data after active substance approval:	
	-	7.8.1. Peracetic acid for PT 1- 6, 11 and 12
	BPC-28-2018-22	7.8.2. Tralopyril for PT 21
	BPC-28-2018-23	7.8.3. S-methoprene for PT 18
	BPC-28-2018-24	
7.9	-	Requesting further information as new test guidelines become available
7.10	BPC-28-2018-25	Systematic literature review for ED assessment

7.11	BPC-28-2018-26	Biocides assessment and RAC opinion on harmonised classification (CLH)	
8.1	BPC-28-2018-21	Update on Union authorisation	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.2	BPC-28-2018-10A	Silver zinc zeolite PT 2	Draft BPC opinion
	BPC-28-2018-10C		Open issues
	BPC-28-2018-30_Room doc 3		Description of exposure categories and scales
	BPC-28-2018-11A	Silver zinc zeolite - PT 7	Draft BPC opinion
	BPC-28-2018-10C		Open issues
	BPC-28-2018-12A	Silver zinc zeolite - PT 9	Draft BPC opinion
	BPC-28-2018-10C		Open issues
7.3	BPC-28-2018-13A	Silver zeolite PT 9	Draft BPC opinion
	BPC-28-2018-10C		Open issues
7.4	BPC-28-2018-14A	Silver copper zeolite PT 9	Draft BPC opinion
	BPC-28-2018-10C		Open issues
7.5	BPC-28-2018-15A	Silver sodium hydrogen zirconium phosphate PT 9	Draft BPC opinion
	BPC-28-2018-10C		Open issues
7.6	BPC-28-2018-16A	ADBAC PT 3	Draft BPC opinion
	BPC-28-2018-16B		Assessment report
	BPC-28-2018-16C		Open issues
	BPC-28-2018-17A	ADBAC PT 4	Draft BPC opinion
	BPC-28-2018-17B		Assessment report
	BPC-28-2018-16C		Open issues
	BPC-28-2018-18A	DDAC PT 3	Draft BPC opinion
	BPC-28-2018-18B		Assessment report
	BPC-28-2018-18C		Open issues
	BPC-28-2018-19A	DDAC PT 4	Draft BPC opinion
	BPC-28-2018-19B		Assessment report
	BPC-28-2018-18C		Open issues
7.7	BPC-28-2018-20A	Icaridine PT 19	Draft BPC opinion
	BPC-28-2018-20B		Assessment report
	BPC-28-2018-20C		Open issues
8.2	BPC-28-2018-27A		Draft BPC opinion
	BPC-28-2018-27B		SPC

	BPC-28-2018-27C	UA: product families containing iodine / PVP-iodine	PAR
	BPC-28-2018-27C1		Confidential annex to PAR
	BPC-28-2018-27C2		Confidential annex MS to PAR
	BPC-28-2018-27D		Open issues
	BPC-28-2018-29_Room doc 2		Section 5.3 regarding emergency measures

12 November 2018
BPC-A-28-2018

Draft agenda
28th meeting of the Biocidal Products Committee (BPC)
11-14 December 2018
ECHA Conference Centre, Annankatu 18, Helsinki
Starts on 11 December at 09:30, ends on 14 December at 13:00

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-28-2018
For agreement

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

4. – Agreement of the minutes and review of actions from BPC-27

BPC-M-27-2018
For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

BPC-28-2018-01
For information

6. – Work programme for BPC

6.1. BPC Work Programme 2018-2019 for active substance approval

BPC-28-2018-02
For information

6.2. BPC Work Programme 2018-2019 for Union authorisation

BPC-28-2018-03

For information

6.3. Outlook for BPC

BPC-28-2018-04

For information

6.4. Status harmonised classification and labelling for active substances

BPC-28-2018-05

For information

6.5. Status ED assessment for active substances

BPC-28-2018-06

For information

7. – Applications for approval of active substances[†]

7.1. Procedural and administrative aspects:

7.1.1. Template BPC opinion for active substance approval

BPC-28-2018-07

For information

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

BPC-28-2018-08

For information

7.1.3. Presentation of PBT status in BPC opinion: potential PBTs

BPC-28-2018-09

For discussion

7.2. Draft BPC opinion on silver zinc zeolite for PT 2, 7 and 9

Previous discussion(s): TM-II-2013, TM-IV-2013, WG-III-2015, WG-III-2016,WG-V-2016, WG-V-2017; BPC-27

PT 2: BPC-28-2018-10A, B, C

PT 7: BPC-28-2018-11A, B, C

PT 9: BPC-28-2018-12A, B, C

For agreement

[†] 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 (AR) 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).

7.3. Draft BPC opinion on silver zeolite for PT 9

Previous discussion(s): WG-V-2017; BPC-27

BPC-28-2018-13A, B, C

For agreement

7.4. Draft BPC opinion on silver copper zeolite for PT 9

Previous discussion(s): WG-V-2017; BPC-27

BPC-28-2018-14A, B, C

For agreement

7.5. Draft BPC opinion on silver sodium hydrogen zirconium phosphate for PT 9

Previous discussion(s): WG-V-2017; BPC-27

BPC-28-2018-15A, B, C

For agreement

7.6. Draft BPC opinion on ADBAC and DDAC for PT 3 and 4

Previous discussion(s): WG-V-2017

ADBAC PT 3: BPC-28-2018-16A, B, C

ADBAC PT 4: BPC-28-2018-17A, B, C

DDAC PT 3: BPC-28-2018-18A, B, C

DDAC PT 4: BPC-28-2018-19A, B, C

For agreement

7.7. Draft BPC opinion on icaridine for PT 19

Previous discussion(s): WG-I-2017

BPC-28-2018-20A, B, C

For agreement

7.8. Revised Assessment Report following the submission of data after active substance approval:

7.8.1. Peracetic acid for PT 1- 6, 11 and 12

BPC-28-2018-21

For agreement

7.8.2. Tralopyril for PT 21

BPC-28-2018-22

For agreement

7.8.3. S-methoprene for PT 18

BPC-28-2018-23

For agreement

7.9. Requesting further information as new test guidelines become available

BPC-28-2018-24

For agreement

7.10. Systematic literature review for ED assessment

BPC-28-2018-25

For agreement

7.11. Biocides assessment and RAC opinion on harmonised classification (CLH)

BPC-28-2018-26

For agreement

Item 8 – Union authorisation**

8.1 Update on Union authorisation

8.2 Draft BPC opinions on Union authorisation applications for a product family containing iodine / PVP-iodine

Previous discussion(s): WG-IV-2018

BPC-28-2018-27A, B, C, D

For adoption

Item 9 – Any other business

Item 10 – Action points and conclusions

For agreement

** 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 Summary of Product Characteristics (SPC) (denoted by B), a draft product assessment report (PAR) (denoted by C) and a document containing open issues to be discussed for the biocidal product or biocidal product familiy (denoted by D).

Provisional time schedule for the

28th meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Annankatu 18, Helsinki

11 December 2018: starts at 09:30; 14 December 2018 ends at 13:00

Please note that the time schedule indicated below is provisional and subject to possible change. The schedule is distributed to participants on a preliminary basis. If needed, follow-up discussions may take place on the following day for BPC opinions.

Tuesday 11 December: morning session

Items 1-5	Opening items and administrative issues	
Item 6	Work programme of the BPC 2018-2019	
	6.1.	BPC Work Programme 2018-2019 for active substance approval
	6.2.	BPC Work Programme 2018-2019 for Union authorisationl
	6.3.	Outlook for BPC
	6.4.	Status harmonised classification and labelling for active substances
	6.5.	Status ED assessment for active substances
Item 7.1.	Procedural and administrative aspects:	
	7.1.1.	Template BPC opinion for active substance approval
	7.1.2.	Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval
	7.1.3.	Presentation of PBT status in BPC opinion: potential PBTs

Tuesday 11 December: afternoon session

Item 7.2-7.5	BPC opinions on silver:	
	7.2.	Draft BPC opinion on silver zinc zeolite for PT 2, 7 and 9
	7.3.	Draft BPC opinion on silver zeolite for PT 9
	7.4.	Draft BPC opinion on silver copper zeolite for PT 9
	7.5.	Draft BPC opinion on silver sodium hydrogen zirconium phosphate for PT 9

Wednesday 12 December: morning session

Item 7.2-7.5 Draft BPC opinions on silver (cont'd)

Wednesday 12 December: afternoon session

Item 7.2-7.5 Draft BPC opinions on silver (cont'd)

Thursday 13 December: morning session

Item 7.6.	Draft BPC opinion on ADBAC and DDAC for PT 3 and 4
Item 7.7.	Draft BPC opinion on icaridine for PT 19

Thursday 13 December: afternoon session

Item 7.7	(cont'd)
Item 7.8.	Revised Assessment Report following the submission of data after active substance approval:
	7.8.1. Peracetic acid for PT 1- 6, 11 and 12
	7.8.2. Tralopyril for PT 21
	7.8.3. S-methoprene for PT 18
Item 7.9.	Requesting further information as new test guidelines become available
Item 7.10.	Systematic literature review for ED assessment
Item 7.11.	Biocides assessment and RAC opinion on harmonised classification (CLH)

Friday 14 December: morning session

Item 8.1	Update on Union authorisation
Item 8.2	Draft BPC opinions on Union authorisation applications for a product family containing iodine / PVP-iodine
Item 9	AOB
Item 10	Action points and conclusions

End of meeting

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