16 October 2018

BPC-M-26-2018

Minutes of the 26th meeting of the Biocidal Products Committee (BPC)

27-28 June 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 26th BPC meeting.

Regarding the BPC membership, the Chairman stated that there is a new BPC member for Denmark, Nina Falk Gregersen. The nominiation of an alternate member for Denmark is pending. There is also a new BPC member for Malta, Joanne Borg-Galea whereas the new alternate BPC member for Malta is the previous BPC member Wayne Giordmaina

The Chairman then informed the BPC members of the participation of 28 members, including 5 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-26-2018_rev2) 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-25

The revised draft minutes from BPC-25 (BPC-M-25-2018), incorporating the comments received, were agreed.

The Chairman noted that the actions from BPC-25 have been carried out.

The Chairman informed the meeting on the assessment of endocrine discupting properties in active substance approval: i) the document discussed at the last BPC meeting entitled "Principles for the assessment of endocrine disrupting properties in active substance approval" was finalised by the SECR and published on the BPC CIRCABC IG as well as the BPC webpage on the ECHA website; ii) the guidance prepared by EFSA and ECHA was finalised and published on the websites of both organisations (for the ECHA website: entitled "Guidance for identification of endocrine disruptors" as part of Volume V Specific Guidance at https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation).

The Chairman asked the attention of the members to the consultation on 21 June by the SECR on the document "Definition of relevant impurities". The consultation is aimed at the APCP, TOX and ENV Working Groups and the BPC. Depending on the comments received the SECR will decide if first Working Group discussions are needed or if the document can directly be scheduled for the BPC meeting in October. The deadline for commenting is 7 August.

Actions:

- **SECR:** to upload the agreed minutes from BPC-25 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 thanked those BPC members who already have submitted their annual declarations to the SECR and reminded those, who have not yet done it, to do it as soon as possible. He also reminded BPC members that the annual declaration of interest will be published on the ECHA website.

The Chairman introduced document BPC-26-2018-01 prepared by ECHA for the Management Board meeting which contains the progress reports for each Committee including the PBT and ED Expert Groups. The Chairman mentioned that improved coordination with respect to CLP, PBT and EDs as requested by the Commisison at the last meeting is under internal discussion within ECHA. With respect to CLP coordination he mentioned that the SECR has prepared an overview of all active substances and their CLP status with respect to harmonised classification. This overview will be presented by the SECR at the next meeting. Related to the coordination with CLH two questions were raised by the members which will be addressed by the SECR at the next meeting.

Actions:

- **Members involved:** to submit their annual declaration of interest to SECR as soon as possible
- **SECR:** to investigate when to apply the combined CLH – BPR template and the requirement for the IUCLID submission in the CLH process.

6. Work Programme for BPC

6.1 BPC Work Programme 2018-2019

6.2 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 31 July 2018 after which an updated version will be published on the ECHA website.

The Chairman stated that:

- For active substance approval the number of opinions scheduled for the Review Programme in 2018 is 43. In addition, 1 BPR new actives, 1 BPD new active, 2 existing active substances submitted under the BPD are scheduled.
- The Commission has returned the following active substances to ECHA for an ED assessment (via an Article 75(1)(g) procedure): cyanamid; chlorophene; salicylic acid; 2-phenoxyethanol; formaldehyde; MBO; HPT; carbendazim; active chlorine generated from sodium chloride by electrolysis and active chlorine released from hypochlorous acid. In total 32 opinions have now been returned.
- For Union authorisation the number of scheduled opinions is 4. This is 13 less compared to the last BPC meeting in April. The Chairman referred to agenda item 8.1 for further discussion.

The Chairman furthermore stated that:

- No draft CARs were submitted for the last process flow which ended 31 May (9 active substances for 21 PTs were expected). This means there are no discussions at the Working Group meeting of November and the first BPC in 2019. Those meetings may be cancelled pending discussions on backlog dossiers or Union authorisations.
- The revised assessment for copper PT 2, 5 and 11 will be tabled for the APCP and TOX WG in November 2018 and the first BPC in 2019. A new proposal for the reference specification will be proposed by the eCA France in these WG meetings.

- The Chairman asked the eCAs with active substances scheduled for discussion at the October BPC meeting (BPC-27) to confirm this planning to the SECR by 15 August 2018.
- SECR presented a short overview on the 'Grip on the Review Programme' project. It was explained that the aim of the current work is to obtain a view on what issues are blocking progress of specific dossiers. However. feedback on how ECHA can improve communication and the presentation of information is very welcome. Once a complete overview has been obtained ECHA will prioritise the issues identified. The current work is only the first step. The long term aim is to improve the interaction between ECHA and Member States, so that issues can be identified as early as possible and ECHA can support the Member States in their obligations with regards to the review programme.

  One member stated that prioritisation of guidance is also on the agenda and that coordination between the two is needed. SECR confirmed that this coordination will take place.
- The Chairman announced that ECHA is planning to organise a workshop on the active substance approval process with a foreseen date of February 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 1st September 2013.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) to the SECR by **31 July 2018**.
- **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 October BPC meeting will remain on track by **15 August 2018**.

7. Applications for approval of active substances

7.1 Draft BPC opinion on DBNPA for PT 4

The Chairman welcomed the applicant and the rapporteur introduced the substance. The ASOs were allowed to be present during the discussion.

The rapporteur informed that an assessment of the ED properties against the new ED criteria has not been performed. The Chairman clarified that the ED assessment aginst the new criteria is required in order to adopt the BPC opinion as the criteria are applicable from 7 June 2018. The Chairman stated that in such a situation the committee is invited to discuss and agree on all other sections of the opinion. The eCA will then be asked by the SECR to perform the ED assessment against the new criteria and return the opinion to the SECR for adoption at the BPC.

The comments on the AR and the draft BPC opinion were discussed. The Committee agreed that the proposed classification as Skin Sensitizer 1B should remain in the assessment.

The Committee agreed with the proposal to consider the metabolite cyanoacetamide (CAM) as “potentially persistent”, although it was recognised that the consideration as “potential” triggers some issues from a regulatory perspective as the ‘category’ of “potential PBT” does not exist within the BPR. The SECR proposed to have a general discussion on this issue in an upcoming BPC meeting. Based on the consideration of CAM as potentially persistent, a new ready biodegradability test on this metabolite will be requested as post-approval data. The BPC agreed that a new soil degradation test was not necessary to conclude on the assessment.

The BPC concluded that since an assessment of disinfectant by-products (DBPs) had not been conducted for the approval of the active substance, at product authorisation the new guidance on DPBs should be used to assess potential DPBs or demonstrate that no DBPs will be formed.

The rest of issues indicated in the open issues table were discussed and agreed by the Committee. The Assessment Report and the BPC opinion were agreed.

Actions:

- **Rapporteur:** to perform the ED assessment and return the opinion and Assessment Report to ECHA.
- **SECR:** to prepare a document for the next BPC on the PBT assessment related to the issue of “potential PBT” substances.

7.2 Draft BPC opinion on chlorfenapyr for PT 18

The Chairman welcomed the applicant and the rapporteur introduced the substance. The ASOs were allowed to be present during the discussion. The rapporteur informed that an assessment of the ED properties against the new ED criteria was not performed as non-approval is proposed. The Chairman noted that this is in line with the current CA guidance and that as chlorfenapyr is a candidate for substitution (toxic and very persistent substance) a public consultation had taken place to identify possible alternatives according to Article 10(3) of the BPR.

The main comments identified in the open issues table related to the Assessment Report were discussed. The proposal from the applicant to refine the PNEC sediment previously agreed by the Environmental Working Group was not supported. The Committee discussed the applicability of potential risk management measures (RMMs) to mitigate the risks to the sediment compartment, in particular the need to restrict the application of the biocidal product to areas that are not wet-cleaned. The applicant explained that due to the use of the product (intended use against ants by professionals), the spots to be treated can be confined.

The SECR informed that in order to achieve a safe use all the steps in the process, including mixing and loading, application and post-application would need to take place in confined settings where emissions to the environment could be controlled.

The BPC members considered that the RMMs are feasible, taking into account that chlorfenapyr-containing products would be used only by professionals (Pest Control Operators). The BPC agreed to use wet wipes to remove spills from non-treated areas resulting from the application of the product, since this would remove the product from the area around the crack and crevice but not from the treated surfaces, therefore not affecting the efficacy of the product. Furthermore, the BPC agreed that the applicator's clothes must be disposable. Consequently, with the set of proposed RMMS there will be no emissions to the environment.

Based on this discussion, a safe use of the product might still be identified with these RMMs and an approval could potentially be proposed for the active substance. The Chairman suggested that a new proposal is brought by the eCA to the Committee considering these new RMMs. The eCA was asked to consider whether the assessment of the ED properties aginst the new criteria could be included in the AR and OPI at the same time as the agreed RMMs.

The BPC discussed several other relevant comments in the Assessment Report.

The Committee noted that the human exposure assessment should be revised in order to conclude whether an acceptable risk for secondary exposure would be identified. Since a post-application step (cleaning with wet wipes) will be included in the assessment based on the new RMMs, the potential exposure for the cleaning step should also be assessed. It was recognised that this exposure would be almost negligible compared to the one occurring in the application step.

The Commission noted that the identification of alternatives for chlorfenapyr being a candidate for substitution should be addressed in a more conclusive manner in the next version of the BPC opinion, in particular considering that most insecticides have already been reviewed. The Chairman indicated that the SECR will work together with the eCA for analysing the input received during the public consultation.

Actions:

- **Rapporteur:** to revise the assessment report and BPC opinion in accordance with the discussions in the BPC and submit this to the SECR.

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

7.3.1 Copper thiocyanate, dicopper oxide and copper flakes (coated with aliphatic acid) for PT 21

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

Actions:

- **Member (FR):** to forward the revised assessment report with the List of Endpoints to the SECR by **15 August 2018**.

7.3.2. Bacillus thuringiensis subsp. Kurstaki for PT 18

The evaluating CA France informed the meeting on the progress on the evaluation of the post approval data. The assessment was discussed at the Ad hoc WG Micro-organisms (WG MO) meeting of 22 May. The WG MO agreed to require some additional data from the applicant, which was provided by the given timeline. The revised assessment is now under commenting by the Ad hoc WG MO. The WG MO agreement is expected by the end of August, in order to present the revised assessment at BPC-27.

Actions:

- **Member (FR):** to prepare the revised Assessment Report with the List of Endpoints for the next BPC

7.4 Requesting further information as new test guidelines become available

The SECR presented the document, noting that it was drafted for two purposes:

1. To ensure that all MSCAs are aware of the guidelines that were not available at the time of dossier submission and completeness check for the Review Programme dossiers, and that now enable in vivo follow-up of positive in vitro genotoxicity results;
2. To raise the question whether it would be possible to finalise the BPC opinion in the absence of the information for which the requirement was identified late in the process.

None of the members supported the proposal to add possibly identified data gaps as post-approval data to the BPC opinion and to approve the respective active substances only for e.g. 5 years. Some members supported postponing the information requirements to the renewal of the active substance approval, noting that requesting, performing and evaluating the additional studies will take a significant amount of time, during which the substances can remain on the market.

Several members were of the view that genotoxicity information is of very high importance and could result in meeting the exclusion criteria. Comparison was also made to the ED criteria, for which such exceptions would not be made. Overall these members considered that genotoxicity information could not be postponed and it would be needed for the BPC opinion. This view was also supported by COM considering that it is stated in the BPR that sufficient data should be provided to assess the exclusion and substitution criteria. One member noted that the proposed postponement of information requirement might be acceptable only if e.g. read-across to similar substances would support non-mutagenicity and the information requirement would be to confirm this.

Some members suggested that there might be special cases for which the information requirement could be postponed, for example if it can be shown that the guidelines would not be applicable or there would be the need to apply restrictions due to the hazard/risk profile of the substance. In such cases it would be better to finalise the BPC opinion and complete the assessment at the renewal stage.

SECR noted that the limited experience with the new guidelines should also be taken into account, as there is less expertise in the eCAs and only limited availability of laboratories capable of performing the studies.

COM reminded of a previous situation in the plant protection products area, where the Ombudsman expressed concerns on the post approval requirements used in the past in approval decisions, and recommended that the Commission should take decision based on complete information. COM further remarked that it would be useful to gather information regarding the numbers of substances affected by the issue referred in SECR's note, what are the tests/studies concerned, the time needed for performing the tests/studies, and if possible information on the number of laboratories able to perform these tests/studies.

Actions:

- **SECR:** to open a Newsgroup for commenting on the document by **15 August 2018** and prepare a revised document for the next BPC meeting.
- **Members**: to consider the active substances for which they are eCA and inform the SECR by **15 August 2018** if there are similar cases to the two presented in the document (local effects driving the assessment and limited data package on mutagenicity leading to a probable data request for the tests described in the document)

7.5. Terminology primary and secondary exposure in the BPC opinion

SECR presented the document indicating that this refers specifically to primary and secondary exposure particulary to treated articles under PT 6,7 and 9. During the discussion different view were exchanged and it was reported that discussions within the MSs have been controversial on whether exposure to treated articles should be considered as secondary. COM pointed out that it would not be consistent to consider for professional user exposure to treated article as primary and for non-professional and consumer as secondary. It was agreed that previous Working Group discussions on this topic should be checked carefully and that there is a need to open a Newsgroup for commenting on the document and to prepare a revised document for the next BPC meeting.

Actions:

- **SECR:** to open a Newsgroup for commenting on the document by **15 August 2018** and prepare a revised document for the next BPC meeting.

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 welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The Chairman explained that there were two separate open issues tables, containing the applicant's comments and the Member States' comments. The rapporteur presented the status of the application.

The discussion focussed on the following main areas:

A. Final assessment of the "corrosivity to metals" study

The Rapporteur introduced their conclusion regarding the assessment of the "corrosivity to metals" study. The BPC members agreed with the conclusion of the Rapporteur.

B. New uses introduced in the PAR and SPC after the Working Group discussions

One BPC member highlighted that there were new uses introduced in the PAR and SPC after the Working Group discussions. The Rapporteur clarified that, based on the Working Group agreement, certain uses have been split due to the different risk mitigation measures for the separate uses.
The Chairman stated that, if new uses and /or new Meta-SPCs occur in the PAR and SPC between the WG and BPC meetings, this should be clearly stated and explained. This is applicable, as a general approach, to all Union authorisation cases. The BPC members agreed on the statement and on the new uses introduced for this product family.

C. Efficacy: virucidal claim for the product uses

The Rapporteur introduced their final conclusion on the use of the products against viruses. Due to the lack of proper control data in the virucidal efficacy test, the majority of the BPC members disagreed with the virucidal claim for this Union authorisation. Thus, it was decided that the virucidal claim should be removed from the PAR and SPC. The Commission reminded the BPC members that their national authorisation decisions should be consistent with this agreement. Due to uncertainties regarding this specific efficacy norm, the SECR agreed to initiate a discussion at the Efficacy Working Group regarding the performing of valid controls. In addition, the SECR reminded the BPC members that in case of any doubts during the evaluation phase, the possibility of early Working Group discussions can be utilized in order to facilitate the review process.

D. Dietary risk assessment

One BPC member pointed out that the dietary risk assessment was not carried out for the worst case scenario for a use merely for manual applications. The Rapporteur explained that for the dietary risk assessment the previous agreements were taken into account and the point raised by the member was closed before the WG discussion. The Chairman pointed out that this point should have been raised and agreed upon during the WG

discussions and since the point was closed previously, the BPC was not the appropriate forum for revising any technical specificities. As a way forward for the use in question, the restriction to 5 manual applications/day/animal was proposed and agreed by the BPC members. Regarding the risk assessment for the daily iodine intake for toddlers, the Rapporteur explained that the assessment was consistent with the previous Union authorisation cases.

The same member questioned the approach to consider iodine coming from other sources via dietary intake when specifying the personal protective equipment. This results in higher requirements regarding the prescribed PPE compared with only considering the biocidal application. In view of this member, this approach does not suit to the approach taken for the risk assessment where only biocidal sources are considered to decide whether there is a safe use. This point was however not discussed as ECHA clarified that the same approach was already taken for earlier Union authorisations containing iodine/PVP-iodine.

E. The items included in the two open issues tables regarding the PAR, SPC and the BPC opinion

All the items included in the two open issues tables were addressed. The BPC opinion, the SPC and the PAR will be revised according to the conclusions taken at the BPC and as reflected in the open issues tables.

In addition, the Chairman informed the BPC members that now the new ED criteria are applicable the BPC opinion shall always state whether the biocidal product (family) contains a substance of concern or not. If the biocidal product (family) contains a substance of concern identified as an ED accoding to the new criteria, the current CA guidance has to be applied (CA-March18-Doc.7.3.b-final).

The BPC opinion, the PAR and the 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 **9 July 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 **9 July 2018**.
- **SECR**: to forward the translated draft SPC to COM by **10 August 2018**.

8.3 Proposal on the “fast-track procedure” on Union authorisation

The SECR indicated that the proposal on the “fast-track procedure”, including the main criteria and critical aspects for the applicability of the approach, was discussed during the BPC-25. After analysing the comments received during the BPC-25 and in the subsequent commenting period, the SECR considered that the objectives sought (streamlining the procedure and reducing the Working Groups’ workload) would not be achieved with the active involvement of the Working Groups in deciding after a commenting period whether the fast-track procedure could be applied. The SECR considered that such involvement of

the Working Group members will not reduce significantly their workload, while the current working procedure already prevents or limits the Working Group discussions on issues already concluded for similar cases.

The SECR acknowledged that the experience acquired so far with the Union authorisation applications is still limited and relates to the simplest possible situation. The initial applications for Union authorisation based on iodine/PVP iodine peer-reviewed so far, represent a unique case of a single use with almost identical use patterns. Moreover, based on the limited number and variety of processed applications, it is difficult for the time being to foresee how often the situation could be applicable in the future.

Nonetheless, the SECR noted that a certain degree of similarity is expected between the applications for products containing for example peracetic acid or hydrogen peroxide and therefore proposed to reconsider by the end of 2019 the possibility to establish a "fast track procedure" for Union authorisation in light of the experience acquired with time and in particular with the applications for products containing peracetic acid or hydrogen peroxide.

The BPC agreed on the proposal.

8.4 Working procedure for applications for major change of a Union authorisation

The SECR presented the newly developed working procedure for major changes to Union Authorisations and indicated that it was modelled on the working procedure for Union Authorisations. The presentation focused on the main points in which the working procedure for major change is different from that of a 'first' union authorisation. These include the removal of the accordance check and discussion at the Working Group. This is done to accommodate the reduced timeline in comparison to the 'first' union authorisation, 90 days compared to 180 days. It was indicated that more communication via R4BP will be considered in line with the earlier discussion on the Union Authorisation procedure.

One member suggested to align with the Union Authorisation working procedure, with a focus on communication via R4BP3. Some doubts were expressed that communication with applicants is left to the eCA. It was mentioned that commenting should not run via WG members but rather via the CA who coordinates the work. Concerns were expressed on the fact that no step is foreseen in case of disagreement between eCA and other MSs to close a point. A major concern was raised about excluding the WG meeting in the process as consequently technical issues may have to be discussed at the BPC meeting. It is clear though that the short timelines make finding a solution difficult.

The SECR indicated that early WG discussions should be considered by eCA as indeed during the peer review phase the timelines are too short to have extensive discussions.

The SECR indicated that indeed R4BP will be considered for communication, in line with the Union Authorisation working procedure. The need to communicate with the CA, rather than with WG members will be explored. SECR recognised that removing the WG meeting from the procedure makes the problem solving among MSCAs more complex, but saw no other solution at the moment.

One other member also would like this working procedure to be aligned as much as possible with the Union Authorisation working procedure and preferred to keep the

accordance check as the added value is recognised. Major changes may not be easy and therefore ECHA's help is useful.

The SECR questioned which criteria should be checked during an accordance check as it is not as straightforward as a 'first' union authorisation. The accordance check will probably have to be tailor-made.

Actions:

- **SECR:** to open a Newsgroup for commenting on the document by **15 August 2018** and prepare a revised document for the next BPC meeting.

8.5 Union authorisation major change applications: cooperation during the evaluation stage

The SECR presented the document which was also produced to be in line with a similar document for Union Authorisation. The evaluation period is 180 days in stead of 365, therefore the intermediate checks by ECHA are taken out and a more dynamic interaction between ECHA and the eCA is proposed.

A member stated that according to the document the eCA should inform the applicant within 15 days of the fee. However, there is no legal deadline and therefore this should rather be a recommendation. The SECR agreed to rephrase it to a recommendation.

Actions:

- **SECR:** to open a Newsgroup for commenting on the document by **15 August 2018** and prepare a revised document for the next BPC meeting.

8.6 Revision of the working procedure for Union authorisation applications

The SECR presented the main changes in the revised version of the working procedure for Union authorisation applications, as described in the document history.

The comments raised by the members concerned the following aspects:

1. The communication tools in the different steps of the procedure are not optimal and preference was expressed to use only R4BP 3. If other platforms would be used, one members asked to distribute all relevant information also via the UA IG on S-CIRCABC and, if information was spread by e-mail, to put the UA contact points of the MS in copy. SECR stated that discussions already took place at the BPC-17, when version 2.0 of the working procedure was agreed, regarding the use of the different communication tools and general support was given to the use of S-CIRCABC for the preparatory phases of Working Groups and BPC meetings. Despite the fact that the display of ad hoc communications is improved in R4BP 3 in terms of clarity on the subject and archiving, the SECR pointed out that the S-CIRCABC platform is still preferable because it provides more flexibility in organising the commenting phases. The SECR added that the Interest Groups are

clearly identified in the revised version of the working procedure every time the use of S-CIRCABC is indicated.

2. It was unclear why the eCA would be in charge of the communication with the applicant, while the SECR has been dealing with this task so far. Nonetheless, the eCA could be in charge of the communication with the applicant, provided that R4BP 3 is used as the communication tool. The SECR stated that the eCA will be in charge of the communication with the applicant in line with the working procedure for active substance approval. The SECR considered that the eCA works more in close contact with the applicant than the SECR and is therefore the best responsible actor to send documents to them and inform about the different steps. The SECR clarified that in the majority of the steps where the eCA is in charge of the communication with the applicant, R4BP 3 is used as the communication tool.
3. In step 9 “Disagreement in closing a point”, the request should be directed to the SECR and the evaluating competent authority using R4BP 3 to make it more traceable. This was agreed.
4. The timeline to provide the redacted final PAR (step 45) has been shortened and it would be preferable that more time (for example, 60 days) is allocated to this task. The SECR agreed to reflect on this possibility.
5. The assessment of the confidentiality requests provided by the applicant should be performed only at the end of the process, when all the comments received during the peer-review are consolidated in the final documents. The SECR stated that the eCA is responsible for assessing the confidentiality requests made by the applicant in the dossier and the PAR and for deciding whether to accept them or not. This should take place during the evaluation phase. However, it is important to make sure that the applicant has the possibility, where relevant, to make confidentiality requests on the sections of the PAR updated after the Working Groups and the BPC meetings. Considering the short timeline of 10-14 days for the eCA to provide the final PAR to the SECR after the BPC meeting, assessing the confidentiality requests made by the applicant each time the PAR is updated during the peer-review process will minimise delays in submitting the documents to the SECR.
6. It was unclear whether an annotated IUCLID file is still needed at the end of the procedure. The SECR confirmed that an annotated IUCLID file is still needed at the end of the procedure.
7. It was questioned whether a draft BPC opinion is needed as part of the draft PAR submitted by the evaluating competent authority to ECHA at the end of the evaluation stage, considering that the draft BPC opinion will be subject to changes during the peer-review process. The SECR acknowledged that the draft BPC opinion would be subject to changes during the peer-review process, but an amendment to the PAR template would be needed to remove the draft BPC opinion from the PAR template. The SECR proposed to keep the PAR template in its present form for the time being.

The BPC agreed on the proposal for the revision of the working procedure for Union authorisation applications.

Actions:

- **SECR**: to finalise the revised working procedure taking the comments made into account and publish it on the BPC CIRCABC IG and the ECHA website.

9. Article 75(1)(g) opinions

9.1 Draft BPC opinion on a product used for temporary preservation of corpses

The SECR introduced the opinion and informed that comments from two BPC members (FI and ES) were received. Following this the BPC member from Spain further explained the background of the Article 3(3) of Regulation (EU) No 528/2012 request by them to the Commission (which was then followed by an Article 75(1)(g) request from the Commission to ECHA). The BPC member stated that the product BioSac 200 is expected to be effective for removing odour, but it is unclear whether it preserves corpses. However, the producer claims corpse preservation. As such, the mode of action is considered to be chemical and so potassium permanganate should be regarded as an active substance. The member recommended the producer to claim only odour removal and not corpse preservation. However, the producer refused and subsequently in the resulting court case in Spain it was concluded that the mode of action is physical. Following this Spain submitted an Article 3(3) request to the Commission. The information on whether the product is efficacious is not available, however the mode of action is assumed to be chemical due to the presence of potassium permanganate.

Several members agreed to the conclusion of the opinion that potassium permanganate within the product BioSac 200 acts via chemical means and can be considered as active substance considering crops preservation takes place. One member did not agree.

The opinion was adopted by majority. One BPC member (FI) filed a minority opinion.

Actions:

- **Member** (FI)**:** to submit to the SECR the minority position by **5 July 2018**.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and forward the adopted opinion to COM by **20 July 2018**.

10. Any Other Business

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11. 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 26th meeting of BPC

27-28 June 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-25	
The revised version of the minutes of BPC-25 was agreed as proposed subject to a minor editorial modification. SECR informed the BPC meeting that the ED guidance prepared by EFSA and ECHA was published on the websites of both organisations.	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website.
Item 5 – Administrative issues	
SECR informed about the on-going activities in relation to the coordination between CLP and BPR on harmonised classification and labelling of active substances.	**SECR:** to investigate when to apply the combined CLH – BPR template and the requirement for the IUCLID submission in the CLH process.
Item 6 - Work programme for BPC	
6.1 Revised Work Programme 2018-2019 **6.2 Outlook for BPC**	
	Members: to send information on any further changes to the Work Programme (WP) to the SECR by **31 July 2018.** **SECR:** on the basis of the changes to update the WP on the ECHA website and in the BPC CIRCABC IG.

Item 7 - Applications for approval of active substances	
7.1 Draft BPC opinion on DBNPA for PT 4	
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. **SECR**: to prepare a document for the next BPC on the PBT assessment related to the issue of "potential PBT" substances.
7.2 Draft BPC opinion on chlorfenapyr for PT 18	
The BPC could not conclude on the draft opinion.	**Rapporteur:** to revise the assessment report and BPC opinion in accordance with the discussions in the BPC and submit this to the SECR.
7.3 Revised Assessment Report following the submission of data after active substance approval	
7.3.1 Copper thiocyanate, dicopper oxide and copper flakes (coated with aliphatic acid) PT 21	
The member from FR informed the BPC about the evaluation of the data submitted after the approval.	**Member (FR):** to forward the revised assessment report with the List of Endpoints to the SECR by **15 August 2018**.
7.3.2 Bacillus thuringiensis subsp. Kurstaki PT 18	
The member from FR informed the BPC about the progress on the evaluation of the data submitted after the approval.	**Member (FR):** to prepare the revised Assessment Report with the List of Endpoints for the next BPC.
7.4 Requesting further information as new test guidelines become available	
The BPC discussed the document.	**SECR:** to open a Newsgroup for commenting on the document by **15 August 2018** and prepare a revised document for the next BPC meeting. **Members**: to consider the active substances for which they are eCA and inform the SECR by **15 August 2018** if there are similar cases to the two presented in the document (local effects driving the assessment and limited data package on mutagenicity leading to a probable data request for the tests described in the document).
7.5 Terminology primary and secondary exposure in the BPC opinion	
The BPC discussed the document.	**SECR:** to open a Newsgroup for commenting on the document by **15 August 2018** and prepare a revised document for the next BPC meeting.

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 **9 July 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 **9 July 2018**. **SECR**: to forward the translated draft SPC to COM by **10 August 2018**.
8.3 Proposal on the "fast-track procedure" on Union authorisation	
The BPC agreed on the proposal.	
8.4 Working procedure for applications for major change of a Union authorisation	
The BPC discussed the document.	**SECR:** to open a Newsgroup for commenting on the document by 15 August 2018 and prepare a revised document for the next BPC meeting.
8.5 Union authorisation major change applications: cooperation during the evaluation stage	
The BPC discussed the document.	**SECR:** to open a Newsgroup for commenting on the document by 15 August 2018 and prepare a revised document for the next BPC meeting.
8.6 Revision of the working procedure for Union authorisation applications	
The BPC agreed on the proposal.	**SECR**: to finalise the revised working procedure and publish it on the BPC CIRCABC IG and the ECHA website.

Item 9 – Article 75(1)(g) opinions	
9.1 Draft BPC opinion on a product used for temporary preservation of corpses	
The BPC adopted by majority the opinion.	**Member** (FI)**:** to submit the minority position to the SECR by **5 July 2018**. **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and forward the adopted opinion to COM by **20 July 2018**.
Item 10 – 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)	
CHEZAU Aurelie (FR)	**Advisers**
COSTIGAN Michael (UK)	GAUSTAD Astrid (NO)
DRAGOIU Simona (RO)	HÄMÄLÄINEN Anna-Maija (FI)
GAVRIEL Alexandros (CY)	LARSEN Jørgen (DK)
GONZALEZ MARQUEZ Maria Luisa (ES)	TIPPING Lee (UK)
GREGERSEN Nina Falk (DK)	VISAN Anke (DE)
HADAM Anna (PL)	WEINHEIMER Viola (DE)
HAHLBECK Edda (SE)	
JAGER Stefanie (DE)	
JOHN Nina (AT)	**Accredited Stakeholder Observers**
KOIVISTO Sanna (FI)	MONTMOREAU Bertrand (CEPA)
LANS Martine (NL)	
MERISTE Anu (EE)	
MIKOLASKOVA Denisa (SK)	**ECHA Staff**
RANDALL Marit (NO)	AIRAKSINEN Antero
RUSCONI Manuel (CH)	ESTEVAN MARTINEZ Carmen
VACEK Tomas (CZ)	GUTIERREZ ALONSO Simon
VAGIAS Vasileios (EL)	JANKA Adel
VAN BERLO Boris (BE)	KENIGSWALD Hugues
VRHOVAC FILIPOVIC Ivana (HR)	KURONEN Terhi
	MULLER Gesine
	PECORINI Chiara
Alternate members	RUGGERI Laura
CARBERRY Stephen (IE)	SZYMANKIEWICZ Katarzyna
CRESTI Raffaella (IT)	VAN DE PLASSCHE Erik
ENSCH Svenja (LU)	VAN GALEN Joost
GIORDMAINA Wayne (MT)	
SZENTGYORGYI Timea (HU)	

Applicants	Apologies
BUCHERT Pascale (Dow Europe GmbH) for DBNPA for PT 4	MIHAI Camelia (CEFIC)
KENT Yvonne (BASF Crop Protection) for chlorfenapyr for PT 18	
VAN CORVEN Danielle (Diversey Europe Operations B.V.) for Union authorisation iodine	
Experts accompanying applicants	
HABEKOST Maike, accompanying KENT Yvonne, for chlorfenapyr for PT 18	

Part IV - List of Annexes

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

Annex II Final agenda of BPC-26

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-26 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2	BPC-A-26-2017_rev2	Draft agenda	
4	BPC-M-25-2018	Draft minutes from BPC-25	
5.2	BPC-26-2018-01	Administrative issues and report from the other Committees	
6.1	BPC-26-2018-02	BPC updated Work Programme 2017-2018	
6.2	BPC-26-2018-03	Outlook for the BPC	
7.3.1	BPC-26-2018-06A	Revised AR	
	BPC-26-2018-06B	Revised specification	
	BPC-26-2018-06C	Revised study summary for Nordox	
7.4	BPC-26-2018-07	Requesting further information as new test guidelines become available	
	BPC-26-2018-15_Room document		
7.5	BPC-26-2018-08	Terminology primary and secondary exposure in the BPC opinion	
8.3	BPC-26-2018-10	Proposal on the “fast-track procedure” on Union authorisation	
8.4	BPC-26-2018-11	Working procedure for applications for major change of a Union authorisation	
8.5	BPC-26-2018-12	Union authorisation major change applications: cooperation during the evaluation stage	
8.6	BPC-26-2018-13	Revision of the working procedure for Union authorisation applications	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.1	BPC-26-2018-04A	DBNPA PT 4	Draft BPC opinion
	BPC-26-2018-04B		Assessment report
	BPC-26-2018-04C		Open issues

7.2	BPC-26-2018-14A	Chlorfenapyr PT 18	Draft BPC opinion
	BPC-26-2018-14B		Assessment report
	BPC-26-2018-14C		Open issues
8.2	BPC-26-2018-09A_rev1	UA: product families containing iodine / PVP-iodine	Draft BPC opinion
	BPC-26-2018-09B_rev1		SPC
	BPC-26-2018-09C_rev1		PAR
	BPC-26-2018-09C1_rev1		Confidential annex to PAR
	BPC-26-2018-09C2_rev1		Confidential annex MS to PAR
	BPC-26-2018-09D		Open issues
	BPC-26-2018-09E		Note eCA on efficacy on virucidal testing
	BPC-26-2018-09F		Note eCA on corrosivity to metals
9.1	BPC-26-2018-14A	Draft BPC opinion on a product used for temporary preservation of corpses	Draft BPC opinion

18 June 2018
BPC-A-26-2018_rev2

Draft agenda
26th meeting of the Biocidal Products Committee (BPC)
27-28 June 2018
ECHA Conference Centre, Annankatu 18, Helsinki
Starts on 27 June at 09:30, ends on 28 June at 16:00

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-26-2018

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-25

BPC-M-25-2018

For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

BPC-26-2018-01

For information

6. – Work programme for BPC

6.1. Revised BPC Work Programme 2018-2019

BPC-26-2018-02

For information

6.2. Outlook for BPC

BPC-26-2018-03

For information

7. – Applications for approval of active substances*

7.1. Draft BPC opinion on DBNPA for PT 4

Previous discussion(s): WG-I 2017 (early WG on EFF), WG-I 2018

BPC-26-2018-04A, B, C

For agreement

7.2. Draft BPC opinion on chlorfenapyr for PT 18

Previous discussion(s): WG-V-2017

BPC-26-2018-05A, B, C, D

For adoption

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

7.3.1. Copper thiocyanate, dicopper oxide and copper flakes (coated with aliphatic acid) for PT 21

BPC-26-2018-06

For agreement

7.3.2. Bacillus thuringiensis subsp. Kurstaki for PT 18

For information

7.4. Requesting further information as new test guidelines become available

BPC-26-2018-07

For information and discussion

7.5. Terminology primary and secondary exposure in the BPC opinion

BPC-26-2018-08

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).

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-II-2018

BPC-26-2018-09A, B, C, D, E, F

For adoption

8.3 Proposal on the "fast-track procedure" on Union authorisation

BPC-26-2018-10

For information

8.4 Working procedure for applications for major change of a Union authorisation

BPC-26-2018-11

For agreement

8.5 Union authorisation major change applications: cooperation during the evaluation stage

BPC-26-2018-12

For agreement

8.6 Revision of the working procedure for Union authorisation applications

BPC-26-2018-13

For agreement

Item 9 – Article 75(1)(g) opinions

9.1 Draft BPC opinion on a product used for temporary preservation of corpses

BPC-26-2018-14A and B

For adoption

** For the discussions of the draft BPC opinions at least the following documents will be distributed: a draft BPC opinion (denoted by A), a draft 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).

Item 10 – Any other business

Item 11 – Action points and conclusions

For agreement

Provisional time schedule for the

26th meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Annankatu 18, Helsinki

27 June 2018: starts at 09:30; 28 June 2018 ends at 16:00

Please note that the time schedule indicated below are 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.

Wednesday 27 June: morning session

Items 1-5	Opening items and administrative issues
Item 6	Work programme of the BPC 2018-2019
Item 7.1	Draft BPC opinion on DBNPA for PT 4

Wednesday 27 June: afternoon session

Item 7.2	Draft BPC opinion on chlorfenapyr for PT 18
Item 7.3	Revised Assessment Report following the submission of data after active substance approval:
	7.3.1. Copper thiocyanate, dicopper oxide and copper flakes (coated with aliphatic acid) for PT 21
	7.3.2. Bacillus thuringiensis subsp. Kurstaki for PT 18
Item 7.4.	Requesting further information as new test guidelines become available
Item 7.5.	Terminology primary and secondary exposure in the BPC opinion

Thursday 28 June: 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 8.3	Proposal on the “fast-track procedure” on Union authorisation
Item 8.4	Working procedure for applications for major change of a Union authorisation
Item 8.5	Union authorisation major change applications: cooperation during the evaluation stage
Item 8.6	Revision of the working procedure for Union authorisation applications

Thursday 28 June: afternoon session

Item 9.1	Draft BPC opinion on a product used for temporary preservation of corpses
Item 10	AOB
Item 11	Action points and conclusions

End of meeting

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