23 June 2014

BPC-M-5-2014

Final minutes of the 5th meeting of the Biocidal Products Committee (BPC)

8-10 April 2014

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chair of the Biocidal Products Committee (BPC), welcomed the participants to the fifth meeting.

The Chair mentioned that the BPC alternate member for Finland, Terhi Kuljukka-Rabb has indicated she will resign from her position by 1 May 2014. The Chair thanked her for her contribution to the work of the BPC.

The Chair informed BPC members of the participation of 24 members including five alternates and one member participating remotely. Five advisers, one representative of the European Commission and three accredited stakeholder organisations (ASOs) were present at the meeting. Apologies were received from three members, one adviser and one ASO (AISE).

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

Participants were informed that the meeting would be recorded solely for the purposes of writing the minutes and that this recording would be destroyed after the agreement of the minutes. The list of attendees is given in Part III of the minutes.

2. Agreement of the agenda

The Chairman introduced the draft agenda (BPC-A-5-2013 rev1) and informed participants about an additional item under item 9, any other business, following a request from one member related to correcting errors in an already adopted assessment report (AR) for DCOIT PT8.

The Chair also proposed to add an any other business agenda item, 'lessons learned' in relation to working with the procedures, deadlines and templates for active substance approval.

The Chair invited any additional items. No other additional items to the agenda were proposed. The agenda was agreed. The final version of the agenda was to be uploaded to the BPC CIRCABC IG as part of the meeting minutes.

The Chair informed participants that items 8.1 and 8.2 will be held in closed session owing to the potentially confidential nature of the items. The ASOs were informed afterwards on the outcome of these closed sessions.

The Chair also informed meeting participants that the meeting will be recorded for the purpose of the minutes and destroyed after the agreement of the minutes.

Four documents were tabled as room documents: BPC-5-2014-01 - Housekeeping and security; BPC-4-2014-06 rev 1– Revised Timeline for active substance approval; a revised draft opinion on tralopyril and comments from several members on the draft opinions. These room documents were to be uploaded to the BPC CIRCABC IG after the meeting.

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

3. Declarations of potential conflicts of interest to the agenda

The Chair invited BPC members, alternates and advisers to declare any potential conflicts of interest in relation to the agreed agenda. None were declared.

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

The revised draft minutes from BPC-4 (BPC-M-4-2013_rev 1) were agreed taking into account the proposed changes by the Commission and an editorial suggestion from one of the members in relation to section 7.3.3. The agreed minutes were to be uploaded to the BPC CIRCABC IG and to the ECHA website after the meeting.

The Chair updated members on the status of the actions arising from BPC-4 and noted most items had been completed and the several outstanding items were to be completed either shortly after the meeting, or for the next meeting.

5. Administrative issues

The Chair thanked members and their alternates for providing their annual declarations of commitment and interest promptly, and noted that the Secretariat (SECR) will carry out the conflict of interest check after the meeting and will contact any members in this regard, where necessary. After the conflict of interest check the new declarations will be published on the ECHA website.

5.1. Housekeeping issues

The SECR highlighted the key aspects of the housekeeping rules (BPC-5-2014-01) including the safety and security rules.

5.2 Changes to CIRCA BC and the functional mailbox

The SECR presented document BPC-5-2014-05 which detailed several administrative proposals for improving the way in which the Committee works with CIRCA BC and with the functional mailbox.

Members welcomed and agreed the proposals in document BPC-5-2014-05. In addition, in relation to the substance documents for discussion at meetings several members asked the SECR to increase the visibility of the most recent version of the documents; to seek ways to distinguish between versions of substance documents and comments on the documents; and to be made aware of what substances are to be discussed sufficiently far in advance to organise comments and decide who will participate in meetings. The SECR agreed to these suggestions.

Concerning access to CIRCA BC, several members asked if a further representative of the Competent Authority (MSCA) could have access to the BPC CIRCA BC in order to facilitate communication within the MSCA. One member also proposed that final versions of opinions, Competent Authority reports (CARs) and assessment reports could be stored together in the folder to be named 'opinions'. The SECR agreed to explore these suggestions before the next meeting.

Actions:

The SECR to review several aspects before the next meeting:

- Highlighting the most recent version of documents before the meeting;
- Access for CA representatives to the BPC CIRCA BC other than members and alternates;
- Possibility of having final versions of opinions, CAR and assessment reports together in the 'opinion' folder in the BPC CIRCA BC;
- Identifying timing of substance discussions 3-4 weeks in advance of meetings.

6. Work programme for BPC for 2014 – 15

The SECR presented the detailed work programme containing the active substance/ product type combinations scheduled for the BPC WG and BPC meetings for 2014 and the first meetings of 2015. The SECR indicated an extract of the detailed work programme will be published on the ECHA website which will include a disclaimer that the programme may be subject to change. Several comments were made by the members on the programme.

Actions:

The SECR to:

- Revise the detailed work programme in the light of comments made at the meeting;
- Publish on ECHA's website an adapted version of the work programme listing the active substance/ PT combinations scheduled for each BPC and WG meeting with a disclaimer that the programme may be subject to changes.
- Members were invited to inform the SECR of any further changes to the Work Programme via the functional mailbox: BPC@echa.europa.eu.

7. Applications for approval of active substances

7.1. Working procedure and templates: update from SECR

The revised BPC template for an opinion on active substance approvals (BPC-5-2014-03) was introduced by the Chair who explained that this new version of the template followed the discussion at BPC-4 and comments received subsequently.

Members welcomed the improvements made in the revised opinion template. In the discussion that followed several modifications to the text were proposed to increase the transparency of the text, to improve the clarity of the relationship between the AR and the BPC opinion and to focus the classification and labelling requirements and the requirements in relation to biocidal products that need to be provided in the BPC opinion. The following aspects were agreed:

- The classification and labelling of the representative product is not required in the BPC opinion for active substances;
- Precautionary statements can be removed from CLH presentation (section 2.1);
- An indication should be included of where the assessment report is publicly located;
- For authorising products (section 2.4) refer only to substance-specific elements;
- Where relevant, a subchapter can be added in section 2.5 to indicate the requirements at product authorisation stage resulting from evaluating a dummy product as a representative product; and
- To not include data requirements that will in any case be required at product authorisation (independent of whether the representative product is a dummy product). These data requirements can be listed in the assessment report.

The Chair referred members for information to document BPC-5-2014-04 concerning the commenting period for draft final CARs. This document had previously been circulated to members and reflected the outcome of the discussion at BPC-4, in which a 30 day commenting period was introduced for draft final CARs for the back log dossiers coming directly to the BPC.

In addition, the Chair reported that the timelines for the active substance approval process had been adjusted as shown in document BPC-5-2014-06 rev1. The adjustments made resulted in bringing forward by several working days the date for the production of the response-to-comments table (RCOM) and the delivery of the updated CAR to the Agency before BPC meetings. The adjustment had been made to allow BPC members to have longer to review the updated CAR before BPC meetings and because of the overlap of the preparations for the BPC Working Groups and the BPC meetings.

Several members pointed to the need to ensure that the updated CAR delivered before BPC meetings contains also the document II level information to allow members to review the full risk assessment for the substance/PT combination. Document BPC-5-2014-06 rev1 and the need to provide the Doc II level information in the updated CAR were agreed.

Actions:

The SECR to revise the template according to the discussion and upload the revised version to the BPC CIRCA BC after the meeting.

SECR to prepare a proposal on the procedure for submission and evaluation for data requirements listed in section 2.5 of the opinion template.

7.2. Draft BPC opinion on permethrin for PT 8

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

As part of the BPC-5 meeting documents, the revised AR had been uploaded to the confidential BPC CIRCA BC IG and the revised draft opinion to the non-confidential BPC CIRCA BC IG before the meeting.

The Chair reported that the CAR for permethrin for use in PT 8 was discussed at the Technical Meeting (TM III 2013) and at the BPC-4 meeting in 2014.

The rapporteur explained the revisions introduced following the discussions at BPC-4. Following a brief discussion of the AR, the revised draft opinion was discussed.

The rapporteur indicated that the proposal for classification for skin sensitisation will be maintained by further specifying 1B following the amended criteria for classification and labelling. In order to know what material was tested, members asked the rapporteur to enter into the document the test material description.

Concerning the risk assessment of the active substance a member mentioned that only the niche scenario, "injection treatment – transmission pole" in the use class 4a, was assessed; the conclusions of this evaluation do not concern the other uses in use class 4a. The rapporteur agreed to specify that this scenario was used in class 4a and that others were not.

Members asked the evaluating Competent Authority (eCA) to request from the ECHA PBT Expert Group advice on the assessment of the P properties of the *cis*-isomer in

permethrin and the consequence for the active substance to fulfil the substitution criteria. The rapporteur agreed to this approach.

Members also made several editorial comments, which are to be corrected.

Concerning the revised draft opinion, members welcomed that the document size was clearly reduced and the clarity increased. The rapporteur explained that the relevant aspects of the AR would also be amended to be consistent with the opinion. Several members and COM proposed to extract other parts of the opinion and to include them in the AR, such the description of the combined exposures from different product-types.

COM also noted that, as stated at the last BPC meeting, there will be a need at CA level to reflect on the appropriateness of having in the proposal for approval (for permethrin for PT 8 and PT18) the standard condition related to treated articles as the substance is a skin sensitiser, as the current approach might need to be revised due to the potential impacts of such condition on the EU market.

The BPC adopted by consensus its opinion on an application for the approval of the active substance permethrin for use in PT 8.

Actions:

The rapporteur to revise the assessment report in accordance with the discussions in the BPC and agreed comments made before the meeting and submit it to the SECR by 22 May.

The 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.

The SECR to forward the adopted opinion to COM by 1 May and publish it on the ECHA website.

7.3. Draft BPC opinion on permethrin for PT 18

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

As part of the BPC-5 meeting documents, the revised AR had been uploaded to the confidential BPC CIRCA BC IG and the revised draft opinion to the non-confidential BPC CIRCA BC IG before the meeting.

The Chair reported that the CAR for permethrin for use in PT 18 was discussed at the Technical Meetings (TM I 2011, TM III 2011 and TM III 2013) and at the BPC-4 meeting in 2014.

The rapporteur explained the revisions specific to this product-type and introduced the revisions following the discussions at BPC-4. Following a brief discussion of the AR, the revised draft opinion was discussed.

One member explained that the wording for the risk mitigation measures must be improved so that the specific situation in the Member States can be taken into account, for example with regards to waste management aspects. The member suggested to add the following phrase to chapter 2.4 of the opinion: "Member states shall ensure that these risk mitigation measures are practical. If the risk cannot be reduced to an acceptable level by the application of these risk mitigation measures, or by other means, products should not be authorised for industrial treatment of textile fibres".

The BPC adopted by consensus its opinion on an application for the approval of the active substance permethrin for use in PT 18.

Actions:

The rapporteur to revise the assessment report in accordance with the discussions in the BPC and agreed comments made before the meeting and submit to the SECR by 22 May.

The 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.

The SECR to forward the adopted opinion to COM by 1 May and publish it on the ECHA website.

7.4 Draft BPC opinion on tralopyril for PT 21

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

The Chair reported that the CAR for tralopyril was discussed at the 52nd CA meeting. Following the introduction of the active substance by the rapporteur the revised AR was discussed. For the persistence assessment, correction of the DT50 values for the aquatic environment to the appropriate temperature (at 12°C and 9°C for freshwater and marine water, respectively) was requested. The implication of a metabolite being potentially persistent was discussed. It was agreed that the active substance would not meet the substitution criteria.

Minor changes to the BPC opinion were also discussed and agreed. Amendments to sections 2.3 and 2.4 were discussed and the revisions were made to these sections and agreed by the BPC the following day.

One member proposed to transfer from section 2.4 to section 2.3 the explanation related to unacceptable risks within marinas and commercial harbours. This member did not disagree with the approval proposition, but wanted to stress in the further approval regulation this key conclusion of the assessment, and that specific national considerations must be taken into account at the product authorisation stage to evaluate the possibility to deliver or not authorisations for biocidal products containing tralopyril used in such areas.

The BPC adopted by consensus its opinion on an application for the approval of the active substance tralopyril for use in PT 21.

Actions:

The rapporteur to revise the assessment report in accordance with the discussions in the BPC and agreed comments made before the meeting and submit to the SECR by 22 May.

The 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.

The SECR to forward the adopted opinion to COM by 1 May and publish it on the ECHA website.

The SECR in consultation with COM to clarify the PBT assessment with respect to the evaluation of metabolites and impurities in relation to the assessment of whether an active substance is a candidate for substitution under Article 10(1).

7.5. Draft BPC opinion on alpha-cypermethrin for PT 18

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

The Chair reported that the CAR for alpha-cypermethrin was discussed at the Technical Meeting (TM I 2013) and at the BPC Environment Working Group I 2014.

The rapporteur introduced the AR and the relevant changes introduced in it. The AR was agreed by the BPC members with minor modifications.

Concerning the opinion, it was reported that the revised draft opinion as submitted by the rapporteur had been restructured following a change in the opinion template. In this connection, it was reported that some additional modifications were to be implemented: the reference to the classification and labelling of a representative product and the precautionary statement will both be removed from the draft opinion.

The opinion was discussed and the key discussion points are summarised in the following paragraphs.

7.5.1 Human health and environmental risk assessment

No major comments were provided to the human health risk assessment part of the assessment. Therefore this section was agreed with some editorial changes.

One member highlighted that cypermethrin is included as a priority substance in the Water Framework Directive (WFD, Directive 2000/60/EC[1]).

The predicted environmental concentration (PEC) for the aquatic compartment established in the risk assessment for alpha-cypermethrin is above the environmental quality standard (EQS) established for cypermethrin in the framework of the WFD.

Also, the assessment factor for the predicted no effect concentration (PNEC) derivation diverges from the one used for the EQS derivation.

The role of the EQS in the active substance approval was discussed, the following points were noted:

- Alpha-cypermethrin CAR was submitted before 1 September 2013 under the Biocidal Product Directive (BPD);
- The decision on the active substance approval will be taken under the BPR following the principles of the BPD and the line of document 'CA-March14-Doc.4.1 - Final - Principles for substance approval.doc';
- The dataset for the derivation of the EQS and for the PNEC derivation may diverge (e.g. new data produced in the context of the alpha-cypermethrin peer review; the EQS is set for all the cypermethrin isomers not only for alpha-cypermethrin);
- An opinion on the EQS derivation from the SCHER Committee[2] is available;
- The monitoring data available to the relevant MSCA may give additional information in support of the BPC opinion-making.

It was concluded that the dataset used for setting the EQS needs to be checked against the dataset used for the PNEC derivation. The discussion on this point will continue in BPC-6.

The general issue of the consequence of a possible non-compliance with an EQS derived under the WFD for the approval needs to be addressed further.

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[1] Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for the Community action in the field of water policy

[2] Scientific Committee on Health and Environmental Risks

7.5.2 Elements to be taken into account when authorising products

Considering the results of the risk assessment for alpha-cypermethrin, it was agreed that the following element must be taken into account when authorising products: when authorising products containing alpha-cypermethrin it must be shown that the concentration of the active substance in the product, the application rate, the frequency of use and its amount allow a safe use regarding the aquatic compartment.

In addition, the representative product included in the AR contains an active substance that was not approved (flufenoxuron), the following statement will be included in the final opinion: "the representative product contains alpha-cypermethrin and flufenoxuron; however the risk assessment was performed on alpha-cypermethrin only and not on the second active substance".

Actions:

COM to clarify at the next CA meeting the consequences of a possible non-compliance (exceeding the EQS derived under the WFD) issue for the approval of an active substance.

The rapporteur to consider the derivation of the EQS for cypermethrin in comparison to the PNEC derivation for alpha-cypermethrin and to modify the draft opinion and assessment report as appropriate and submit to the SECR by 20 May.

Members to check whether monitoring data is available and provide to SECR and the eCA as soon as possible.

The SECR to include the substance on the agenda for adoption at the next meeting.

7.6 Draft BPC opinion on folpet for PT 6, PT 7 and PT 9

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

The Chair reported that folpet was discussed at the Technical Meeting (TM III 2012) and at the BPC Environment Working Group I 2014.

The Rapporteur introduced the changes that had been introduced in the AR and gave an overview of the main outstanding issues related to these active substance/PT combinations.

7.6.1 Classification and labelling

One member suggested the rapporteur to consider the possibility of submitting a CLH dossier to ECHA to clarify the classification for skin corrosion/irritation and reproductive toxicity. The rapporteur stated that this possibility may be further considered, but the need to revise the existing entry in Annex VI to CLP Regulation (harmonised classification and labelling entry) was not identified. It was specified that the possible submission of a CLH dossier will not stop the active substance peer review process and therefore the proposal to submit a CLH proposal was not supported.

7.6.2 Human health risk assessment

It was highlighted that revisions in the human health risk assessment are needed. In particular, the risk for non-professionals needs to be further addressed for PT6 and PT7. In addition for PT 9, the fact that the leaching from polymers is negligible needs to be further substantiated in the AR.

In general, all the comments received prior BPC-5 and the previous agreements in the technical meeting need to be considered.

7.6.3 Environmental risk assessment

It was highlighted that some points would need to be further addressed for all the product-types; in particular, the risk assessment for the terrestrial compartment needs to be re-calculated considering service life of five years for PT 6 and PT 7 and of ten to 20 years for PT 9. Also the groundwater risk after direct release to soil needs to be assessed. Finally, although folpet is metabolised rapidly to several metabolites, the risk assessment is still based on folpet. This point needs to be further addressed.
In general, all the comments received prior to BPC-5 and the previous agreements in TM and BPC WG discussions need to be considered.

In conclusion, the BPC did not agree with the proposed assessment reports due to the major revisions to be implemented. The opinions for these active substance/PTs combinations will be discussed together with the revised assessment reports at BPC-6.

Actions:
The rapporteur to modify the assessment report, document II and draft opinion as appropriate and submit to the SECR by 20 May.

The SECR to include the substance on the agenda for adoption at the next meeting.

8. Requests according to Article 75(1)(g) of the BPR (Closed Sessions)

8.1. HeiQ AGS-20

The Chair welcomed the applicant and an accompanying expert for this item and explained that this session was closed because confidential business information may be discussed during the session.

The rapporteur introduced this item and explained that COM had posed three questions to the BPC concerning HeiQ AGS-20: (1) with regard to the biocidal product HeiQ AGS-20, should silver or silver adsorbed on silicon dioxide be considered as the active substance? (2) would this active substance meet the definition of a nanomaterial, as provided in Article 3(1)(z) of Regulation (EU) No 528/2012? and (3) if this active substance meets the definition of a nanomaterial what should be its specifications? The rapporteur noted a first draft of the BPC opinion had been circulated on 10 March for comments and a second version (revision 1) had been made available to members with the meeting documents at the end of March.

A discussion took place in which the following main issues below were raised. For question 1, there was a consensus amongst BPC members that that the composite material should be defined as the active substance. However, there was some discussion on the most appropriate name to be included for this material in the Review Programme. The BPC concluded that the name 'silver adsorbed on silicon dioxide' should be used for now.

In relation to question 2, the BPC agreed that the aggregate consisting of primary particles of silicon dioxide and elemental silver conforms to the provisions in Article 3(1)(z) of the BPR. There was a further discussion however on the interpretation of recital 14 to the Commission Recommendation on the definition of a nanomaterial[3] and whether its purpose is to exclude particulate materials such as AGS-20. After discussion it was agreed that this is not the case and that AGS-20 shall be regarded as a nanomaterial as defined in BPR.

[3] Commission Regulation 2011/696/EU of 18 October 2011.

Concerning question 3, BPC members concluded that it is premature to discuss the specification prior to the evaluation phase of the active substance under the Review Regulation. However, in line with the earlier approval of silicon dioxide as a nanomaterial under the BPR, the specification for silver adsorbed on silicon dioxide could outline that it is a stable aggregate with particle size 1-50 µm, containing primary particles in the nanoscale and a volume specific surface area > 60 m²/cm3.

The applicant agreed to work further on the proposed temporary name for AGS-20 identified in the response to question 1, with a view to having a CAS number assigned to this name.

The BPC adopted by consensus its opinion on HeiQ AGS-20.

Actions:

The rapporteur to revise the draft opinion in accordance with the discussions in the BPC and submit the revised opinion to the SECR by 22 April.

The SECR to carry out an editorial check and confidentiality check in consultation with the rapporteur and applicant.

The SECR to forward the adopted opinion to COM by 30 April and publish it on the ECHA website.

8.2. Polymeric binder

The Chair welcomed the applicant and an accompanying expert for this item and explained that this session was closed because confidential business information may be discussed during the session.

A discussion took place in which several aspects were discussed as reported below. The rapporteur introduced this item and explained that the Commission had posed three questions concerning the polymeric binder: (1) With regard to the polymeric binder, does it contribute to the anti-microbial properties of paints in which it may be incorporated? (2) If so, do these properties result from the action of an active substance in the meaning of Article 3(1)(c) of the BPR? And (3) if so, what is the identity of that active substance? A first draft opinion was produced and following a commenting round a second draft opinion had been produced for adoption at this meeting.

A discussion took place in which several aspects were discussed as reported below. For question 1, with regard to the polymeric binder contributing to the anti-microbial properties of the paint in which it may be incorporated, the meeting agreed without further comments.

In relation to question 2, the meeting also agreed that these properties result from the action of an active substance in the meaning of Article 3(1)(c) of the BPR.

Concerning question 3 on the identity of the active substance, the two proposals by the rapporteur were discussed. In option 1, the active substance is formed in-situ in the paint by a chemical reaction of all three constituents. By this reaction a spatial configuration is generated which enables the anti-microbial activity. In option 2, the active substance is the polymeric binder that is principally active but shows no anti-microbial activity due to steric hindrance.

Most of the members agreed with option 1, however from the practical point of view this option could be a very cumbersome solution. The consequence from option 1 is a high number of active substances that would be subject of an approval. Option 2 was

disregarded since it would in principle conflict with the definition of an active under the BPR.

The rapporteur suggested an alternative option defining the active substance as system of the three components. This was agreed and the rapporteur will remove option 2 from the opinion and redraft option 1 to include the description of the system of the polymer which is in situ formed from the constituents.

The BPC adopted by consensus its opinion on the Polymer binder.

Actions:

The rapporteur was to revise the draft opinion in accordance with the discussions in the BPC and submit the revised opinion to the SECR by 22 April.

The SECR to carry out an editorial check and confidentiality check in consultation with the rapporteur and applicant.

The SECR to forward the adopted opinion to COM by 30 April and publish it on the ECHA website.

9. Any other business

9.1. Update to ECHA guidance for preparing CLH dossiers

The SECR noted that a draft update to the ECHA guidance on the preparation of dossiers for harmonised classification and labelling had been circulated to BPC members for their comments. It was also noted that in future, the BPC will be consulted on relevant developing guidance documents and members are invited to consider these documents where appropriate.

9.2 Correcting inaccuracies in assessment reports for approved active substances

One member introduced this item and informed BPC members that following the previous agreement of the AR for DCOIT/PT 8, some errors had subsequently been detected in the list of endpoints when considering another product-type. The member also noted that the applicant was fully aware of the issue.

Another member noted it would be beneficial to have a document to summarise the actions to be taken when additional data becomes available after approval..

The Chair thanked members for the information and confirmed the SECR will make available to the BPC the AR for DCOIT PT8 with a corrected list of end points.

Action:

The SECR to make available the AR for DCOIT PT8 with a corrected list of end points.

9.3 Lessons learnt so far in the BPC when applying the procedures and working approach for applications for the approval of active substances

The Chair introduced this item explaining that the BPC had worked with the procedures and templates for considering applications for active substance approval for several meetings and it was opportune to collect feedback on the lesson learned thus far.

Members raised a number of points that are summarised below. In general members appreciated the way in which the new system was working and the assistance of the Secretariat in this respect. Several members highlighted the need to apply the original

intention that the BPC WGs will wherever possible resolve as many of the scientific and technical issues as possible. These non-contentious issues would then not be discussed at the BPC ('A' points). The BPC will then focus its discussion on the outstanding issues that have wider or strategic implications ('B' points). Towards achieving this approach, the Secretariat was encouraged to select the B discussion points together with the relevant eCAs and communicate them to members before a meeting.

Several members commented on the timing and presentation of substance documents. In particular, members agreed the importance of having the 17 day period before the meeting to consider and provide comments on substance documents. A number of members also asked the Secretariat to seek ways to improve the clarity of the presentation of substance documents, for example by indicating the version of each document and separating the draft opinions and ARs from the member comments of the documents. To further improve transparency, one member asked if documents uploaded to the CIRCA BC TM could be accompanied by a notification?

Another member highlighted the need to share more equitably the growing workload of the BPC. One mechanism to assist this could be the use of co-rapporteurs.

The accredited stakeholder organisation (ASO) representing the animal welfare organisations, requested on behalf of some ASOs, access to certain documents under discussion in the BPC working groups.

The Chair thanked members for their feedback and noted the Secretariat would explore these aspects further.

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 Anna

Agreed on 10 April 2014 at the 5th meeting of BPC

8-10 April 2014

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
2 - Agreement of the agenda	
The agenda was agreed with several additions to any other business.	**SECR** to upload the agreed agenda to BPC CIRCABC as part of the meeting minutes.
4 - Agreement of the draft minutes and follow up of actions from BPC-4	
The revised version of the minutes of BPC-4 was agreed subject to an editorial modification.	**SECR** to upload the agreed minutes to the BPC CIRCABC and to the ECHA website after the meeting.
5.2 Changes to BPC CIRCABC and the functional mailbox	
The proposed changes in document BPC-5-2014-05 were agreed.	**SECR** to review several aspects before the next meeting: • Highlighting the most recent version of documents before the meeting; • Access for CA representatives to the BPC CIRCABC other than members and alternates; • Possibility of having final versions of opinions, CAR and assessment reports together in the 'opinion' folder in the BPC CIRCABC; • Identifying timing of substance discussions 3-4 weeks in advance of meetings.
6 - Work programme for BPC for 2014 – 2015	
	SECR to • Revise the work programme in the light of comments made at the meeting; • Publish an adapted version of the work programme listing the active substance/ PT combinations scheduled for each BPC and WG meeting with a disclaimer that the programme may be subject to changes. **Members** are invited to inform the SECR of any further changes to the Work Programme.
7 - Applications for approval of active substances	
7.1 Working procedure and templates	
The revised opinion template (BPC-5-2014-03) was agreed subject to several modifications: • The harmonised classification and labelling of the representative product will not be	**SECR** to revise the template according to the discussion and upload the revised version to the BPC CIRCABC after the meeting. **SECR** to prepare a proposal on the procedure for

required; • Precautionary statements can be removed from CLH presentation (section 2.1); • Indicate where assessment report is publicly located; • For authorising products (section 2.4) refer only to substance- specific elements; • Where relevant, add a subchapter in section 2.5 to indicate the requirements at product authorisation resulting from evaluating a dummy product as a representative product; • To not include data requirements that will in any case be required at product authorisation (independent of whether the representative product is a dummy product). These data requirements can be listed in the assessment report. The revised timelines for the active substance approval (BPC-5-2014-06) was agreed. It was also agreed that the CAR to be submitted includes not only the assessment report but also document II.	submission and evaluation for data requirements listed in section 2.5 of the OPI template.
7.2 Draft BPC opinion on permethrin for PT 8	
The BPC adopted by consensus its opinion on an application for the approval of the active substance permethrin for PT 8.	**Rapporteur** to revise the assessment report in accordance with the discussions in the BPC and agreed comments made before the meeting and submit to the SECR by 22 May. **SECR** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR** to forward the adopted opinion to COM by 1 May and publish it on the ECHA website.
7.3 Draft BPC opinion on permethrin for PT 18	
The BPC adopted by consensus its opinion on an application for the approval of the active substance permethrin for PT 18.	**Rapporteur** to revise the assessment report in accordance with the discussions in the BPC and agreed comments made before the meeting and submit to the SECR **by 22 May**. **SECR** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR** to forward the adopted opinion to COM **by 1 May** and publish it on the ECHA website.
7.4 Draft BPC opinion on tralopyril for PT 21	
The BPC adopted by consensus its opinion on an application for the approval of the active substance tralopyril for PT 21.	**Rapporteur** to revise the assessment report in accordance with the discussions in the BPC and agreed comments made before the meeting and submit to the SECR **by 22 May**. **SECR** to revise the draft opinion in accordance with the discussions in the BPC and carry out an

	editorial check in consultation with the rapporteur. **SECR** to forward the adopted opinion to COM **by 1 May** and publish it on the ECHA website. **SECR** in consultation with COM to clarify the PBT assessment with respect to the evaluation of metabolites and impurities in relation to the assessment of whether an active substance is a candidate for substitution under Article 10(1).
7.5 Draft BPC opinion on alpha-cypermethrin for PT 18	
The BPC agreed in principle by consensus its opinion on an application for the approval of the active substance alpha-cypermethrin for PT 18. This is subject to further consideration of the influence of the comparison with the environmental quality standard (EQS) established in the Water Framework Directive for cypermethrin and the environmental risk assessment.	**COM** to clarify the consequences of exceeding the EQS on opinions adopted by the BPC at the next CA meeting. **Rapporteur** to consider the derivation of the EQS for cypermethrin in comparison to the PNEC derivation for alpha-cypermethrin and modify the draft opinion and assessment report as appropriate and submit to the SECR **by 20 May**. **Members** to check whether monitoring data is available and provide to SECR and the eCA as soon as possible. **SECR** to include the substance on the agenda for adoption at the next meeting.
7.6 Draft BPC opinion on folpet for PT 6	
BPC noted the need to clarify the following aspects in the assessment report and draft opinion: • Risk assessment of non-professional uses using the appropriate model; • Risk assessment for the terrestrial compartment to be re-calculated considering service life of 5 years instead of 1 year; • Groundwater risk after direct release to soil to be assessed; • All the comments received prior BPC-5 and the previous agreements in TM and BPC WG discussions to be considered.	**Rapporteur** to modify the assessment report, document II and draft opinion as appropriate and submit to the SECR **by 20 May**. **SECR** to include the substance on the agenda for adoption at the next meeting.
7.7 Draft BPC opinion on folpet for PT 7	
BPC noted the need to clarify the following aspects in the assessment report and draft opinion: • Risk assessment of non-professional uses using the appropriate model; • Risk assessment for the terrestrial compartment to be re-calculated considering service life of 5 years instead of 1 year; • Groundwater risk after direct release to soil to be assessed; • All the comments received prior BPC-5 and	**Rapporteur** to modify the assessment report, document II and draft opinion as appropriate and submit to the SECR **by 20 May**. **SECR** to include the substance on the agenda for adoption at the next meeting.

the previous agreements in TM and BPC WG discussions to be considered.	
7.8 Draft BPC opinion on folpet for PT 9	
The BPC noted the need to clarify the following aspects in the assessment report and draft opinion: • Clarification whether local risks for non-professionals are of concern; • Statement that the leaching from polymers is negligible to be further substantiated; • Risk assessment for the terrestrial compartment to be re-calculated considering service life of 10-20 years instead of 1 year; • Groundwater risk after direct release to soil to be assessed; • All the comments received prior BPC-5 and the previous agreements in TM and BPC WG discussions to be considered.	**Rapporteur** to modify the assessment report, document II and draft opinion as appropriate and submit to the SECR **by 20 May**. **SECR** to include the substance on the agenda for adoption at the next meeting.
8 - Requests according to Article 75(1)(g) of the BPR – Closed session	
8.1 HeiQ AGS-20	
The BPC adopted by consensus its opinion on HeiQ AGS-20.	**Rapporteur** to revise the draft opinion in accordance with the discussions in the BPC and submit the revised opinion to the SECR **by 22 April.** **SECR** to carry out an editorial check and confidentiality check in consultation with the rapporteur and applicant **SECR** to forward the adopted opinion to COM **by 30 April** and publish it on the ECHA website.
8.2 Polymeric binder	
The BPC adopted by consensus its opinion on the polymeric binder.	**Rapporteur** to revise the draft opinion in accordance with the discussions in the BPC and submit the revised opinion to the SECR **by 22 April.** **SECR** to carry out an editorial check and confidentiality check in consultation with the rapporteur and applicant. **SECR** to forward the adopted opinion to COM **by 30 April** and publish it on the ECHA website.
Item 9 – AOB	
9.1 DCOIT PT8	
	SECR to make available the assessment report for DCOIT PT8 with the corrected list of end points.

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Part III - List of Attendees

Members
ALMEIDA Ines (PT)
BERTAGNA Pierre-Loic (FR)
CZAKÓ Klára Mária (HU)
DONS Christian (NO)
DRAGOIU Simona (RO)
GONZÁLEZ MÁRRQUEZ María Luisa (ES)
HARRISON John (IE)
HEESCHE-WAGNER Kerstin (DE)
IAKOVIDOU Mary (SE)
LARSEN Jørgen (DK)
MAJUS Saulius (LT)
MERISTE Anu (EE)
NELEMANS Maartje (NL)
RUBBIANI Maristella (IT)
SPATNY Nina (AT)
TERNIFI Vesna (SL)
TUUSA Tiina (FI)
VAN BERLO Boris (BE) (remotely)
ZOUNOS Athanassios (EL)
Alternate
AZDAD Karima (BE)
CHROBAK Robert (PL)
COSTIGAN Michael (UK)
GAVRIEL Alexandros (CY)
TURK Rajka (CR)
Advisers
BRANDT Charlotte (BE)
CHEZEAU Aurelie (FR)
KOMEN Corine (NL)
ÖSTERWALL Christoffer (SE)
PLATTNER Edmund (AT)
Commission
CHATELIN Ludovic

ECHA Staff
AIRAKSINEN Antero
AJAO Peter
BARMAZ Stefania
FURHMANN Anna
HOLLINS Steve
JANOSSY Judit
MATTHES Jochen
VAN DE PLASSCHE Erik
Accredited Stakeholder Organisations
BRUYNDONCKX Raf (CEFIC)
LEROY Didier (CEPE)
REID Kirsty (Three animal welfare organisations)
Applicants
AHLFORD Kristina (Sumitomo Chemicals UK) PLC – permethrin PT 8 and 18
AZMON Adi (Adama Agricultural Solutions Ltd) folpet PT 6, 7, and 9
BLANCQUAERT Jean-Pierre (Tagros Chemicals India Limited, India) – permethrin PT 8 & 18 and polymeric binder
GRAY Adrian (Janssen Pharmaceutica NV) - tralopyril
McKAY Mark (HeiQ Materials AG) HeiQ AGS-20
NIGGEWEG Ricarda (BASF) – alpha cypermethrin
THOMAS Jean-Christophe (Bayer S.A.S - Environmental Science) – permethrin PT 8 & 18
Experts accompanying applicants
GOODYEAR Andrew (accompanying McKAY Mark) for HeiQ AGS-20
LAWSON Jane (accompanying BLANCQUAERT Jean-Pierre) for polymeric binder
STRUPP Christian (accompanying AZMON Adi) for folpet PT 6, 7, and 9
Apologies
BUSUTTIL Ingrid (MT)
JANTONE Anta (LT)
KULJUKKA-RABB Terhi (FI)
ZIGRAND Jeff (LU)
KILLIAN Karin (COM)
OLEDZKA Gosia (A.I.S.E)

Part IV - List of Annexes

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

Annex II Final agenda

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-5 meeting

Number	**Title**
BPC-A-5-2014 rev1	Draft agenda
BPC-M-4-2014 rev1	Draft minutes from BPC-4
BPC/5/2014/01 (Room document)	Housekeeping issues
BPC/5/2014/02	Work programme for BPC for 2014
BPC/5/2014/03	Revised OPI template for Review Programme existing active substance CARs before 1 September 2013
BPC/5/2014/04	Commenting period for draft final CARs
BPC/5/2014/05	Changes to CIRCABC: BPC and the functional mailbox
BPC/5/2014/06 rev 1 (Room document)	Revised timeline for active substance approval

Annex II

BPC-A-5-2014 FINAL
Agreed at BPC-5
8 April 2014

Final agenda
5th meeting of the Biocidal Products Committee (BPC)

8-10 April 2014
ECHA Conference Centre (Annankatu 18, Helsinki)
8 April: starts at 9:30
10 April: ends at 13.00

Item 1 – Welcome and apologies

Item 2 – Agreement of the agenda

BPC-A-5-2014 rev1
For agreement

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

Item 4 – Agreement of the draft minutes from BPC-4

BPC-M-4-2013
For agreement

Item 5 – Administrative issues

5.1 Housekeeping issues

BPC-5-2014-01
(Room document)
For information

5.2 Changes to CIRCA BC and the functional mailbox

BPC-5-2014-05
For agreement

Item 6 – Work programme for BPC for 2014-15

BPC-5-2014-02

For information

Item 7 – Applications for approval of active substances

7.1 Working procedure and templates: update from SECR

- Revised opinion template (BPC-5-2014-03)

For agreement

- Commenting period for draft final CARs (BPC-5-2014-04)

For information

- Revised timeline for active substance approval

(BPC-5-2014-06 rev 1 Room document)

For information

7.2 Draft BPC opinion on permethrin for PT 08

Previous discussion(s): BPC-4 ***For adoption***

7.3 Draft BPC opinion on permethrin for PT 18

Previous discussion(s): BPC-4 ***For adoption***

7.4 Draft BPC opinion on tralopyril for PT 21

Previous discussion(s): 52nd CA (July 2013) ***For adoption***

7.5 Draft BPC opinion on alpha-cypermethrin for PT 18

Previous discussion(s): TM I 2013, WG-I (Env) ***For adoption***

7.6 Draft BPC opinion on folpet for PT 06

Previous discussion(s): TM III 2012, WG-I (Env) ***For adoption***

7.7 Draft BPC opinion on folpet for PT 07

Previous discussion(s): TM III 2012, WG-I (Env) ***For adoption***

7.8 Draft BPC opinion on folpet for PT 09

Previous discussion(s): TM III 2012, WG-I (Env) ***For adoption***

Item 8 – Requests according to Article 75(1)(g) of the BPR – CLOSED SESSION

8.1 HeiQ AGS-20

For discussion

8.2 Polymeric binder

For adoption

Item 9 – AOB

9.1 Update to ECHA guidance for preparing CLH dossiers

For information

9.2 Corrections in assessment reports for already approved active substance/PT combinations ***For information***

9.3 Lessons learned in relation to considering applications for the approval of active substance/PT combinations

For discussion

Item 10 – Agreement of the action points and conclusions

For agreement

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