8 October 2014

BPC-M-6-2014

Final minutes of the 6th meeting of the Biocidal Products Committee (BPC)

16-19 June 2014

Part I - Summary Record of the Proceedings

1. Welcome and apologies

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

The Chair informed participants that the UK member, Nicola Gregg and her alternate, Michael Costigan have exchanged their roles in BPC: Michael Costigan is now the BPC member and Nicola Gregg is the alternate member. The Chairman thanked Nicola for her contribution to the establishment and early operational phases of the BPC.

The Chair welcomed the Latvian alternate member, Julija Brovkina that has been appointed recently and was attending the meeting for the first time.

The Chair also communicated that the Czech Republic has appointed a member, Tomas Vacek and an alternate member, Jan Mikolas. Also the Slovak Republic has appointed a member, Denisa Mikolaskova, and an alternate member, Jana Chmelikova.

The Chair informed BPC members of the participation of 23 members including 2 alternates and one member participating remotely. 14 advisers, two representatives of the European Commission and three representatives from accredited stakeholder organisations (ASOs) were present at the meeting. Apologies were received from four members, and one ASO (CEPE).

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.

Finally, the Chair noted that Peter Ajao from the Secretariat was leaving ECHA after a temporary period of employment. He was thanked for his contribution to the work of the BPC.

2. Agreement of the agenda

The Chair introduced the final draft agenda (BPC-A-6-2014) and informed participants about two additional items requested to be consider under any other business (AOB). These items followed a request from a member and related to clarification by ECHA of the use of WebEx at BPC Working Group (WG) and BPC meetings and the implementation of new guidance to the active substance approval process. In addition, the Secretariat proposed two AOB items: developments on the biocides budget and an item that arose later in the meeting, the interpretation of voting provisions in the BPC Rules of Procedure (RoPs).

The Chair invited any additional items. The following items were agreed to be added under AOB. One member requested an item on how to process Competent Authority Reports (CARs) submitted after 1 September 2013 meeting the substitution criteria. The Chair agreed for this point to be added. An adviser requested the Secretariat to consider increasing the time for providing comments on draft opinions before meetings.

Another member requested that it would now be opportune to review the approach and process for ad hoc follow-up discussions that take place if there are unresolved scientific or technical points following BPC WG meetings. The Chair confirmed the Secretariat would review this part of the process in the context of reviewing the procedure for active substance approval in the BPC WG meetings.

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 also informed meeting participants that the meeting will be recorded for the purpose of the minutes and destroyed after the agreement of the minutes. The list of meeting documents and the final agenda are included in Part IV of these minutes.

Actions:

The Secretariat (SECR) agreed to review the ad hoc follow-up in the context of the BPC WGs for the active substance approval process.

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-5

The revised draft minutes from BPC-5 (BPC-M-5-2014_rev 1) were agreed taking into account the proposed changes by the Commission and from several members. 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-5 and noted most items had been completed. One member had requested the possibility of having the final BPC opinions, assessment reports (ARs) and CARs together in the BPC CIRCABC IG (item 5.2). The Chair noted that this option had been considered but since the existing TM CIRCABC IG is familiar to all members, this would continue to be used to store final versions of CARs and ARs. Nevertheless, final versions of BPC opinions will be stored in the BPC CIRCABC IG. In response to item 9.1 concerning making a corrected version of the AR for DCOIT PT 8 available, this had been uploaded to the TM CIRCABC IG.

One member enquired whether there had been any progress in relation to item 7.4, namely to clarify how to take into account metabolites and impurities in the PBT assessment and whether consequently an active substance is a candidate for substitution under Article 10(1) of the Biocidal Products Regulation (BPR). The Chair clarified that ECHA is preparing a document on this for the next biocides Competent Authority meeting in September.

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 Changes to CIRCA BC and other administrative issues

Following the discussion at the previous meeting the SECR confirmed that the proposed re-structuring of the BPC CIRCABC IG had been effected, newsgroups with a notification functionality had been used for members' comments during the preparation of this meeting and the address of the functional mailbox for the BPC had been changed to the simpler form previously proposed: bpc@echa.europa.eu. Concerning the request for increased visibility of substance documents, the format

'rev x' will be used to distinguish between different versions in future and for the next meeting substance documents will be numbered.

Given the budgetary constraints the SECR was considering a number of measures to decrease the overall expenditure related to meetings. Accordingly, members were asked to consider if it would be possible to bring forward by one week the date when the invitation is sent out and therefore registration is initiated. Alternatively, members were asked to consider if the period for registration could be shortened from two weeks to one. It was agreed, where practicable, to bring forward by one week the date when the invitations are sent out to five weeks preceding a meeting. In addition to assist members, it was agreed to notify participants in advance of forthcoming meetings the anticipated length and date for the registration to begin.

The SECR also noted that a number of advisers had been requested for the purposes of access of the BPC CIRCA BC IG. These would be granted access in the period after the meeting.

Actions:

The SECR to confirm the number of meeting days and when the invitation will be sent out.

5.3 BPC declaration of interest and the BPC Rules of Procedure

The SECR explained that the ECHA Management Board at its meeting of 20 March 2014 had revised the ECHA policy for managing potential conflicts of interest. Consequently there were two key changes for BPC members to be aware of as set out below.

There is a new declaration of interest (DoI) template that will replace Annex 2 to the BPC RoPs and a new version of the BPC RoPs has been prepared (BPC-6-2014-01) which includes this new DoI. The new template should be used when DoIs are updated next year, or if new members are appointed.

The second aspect for members to be aware of is that the ECHA policy now explicitly states that members or alternates that have not submitted annual DoIs shall not take part in meetings of an ECHA body like the BPC.

6. Work Programme for BPC for 2014 – 15

The SECR introduced the BPC Work Programme for 2014 – 2015 (BPC-6-2014-03), asking members to inform the SECR of any changes. The SECR indicated that some of the meetings, either the BPC or the BPC WGs, contain currently a relatively high number of active substance/PT combinations. The SECR also indicated an adapted version of the Work Programme, i.e. listing the active substance/PT combinations for each meeting with a disclaimer included stating that the programme may be subject to changes, has been published on the ECHA website. COM asked if the SECR can also make available information on the status, where relevant, of the classification and labelling, persistence, bioaccumulation and toxicity (PBT) and endocrine disruption (ED) processes, as well as the planning for the discussions in RAC of related active substances. The SECR stated this information is already available in the overviews prepared several meetings ago.

Following a question from an ASO (CEFIC) the SECR stated that it is the intention to start applying the BPC Code of Conduct for applicants from the next meeting (BPC-7) onwards.

Actions:

The SECR to:

- Apply from BPC-7 onwards the mechanism for engaging applicants specified in the BPC Code of conduct for applicants and highlight this on the ECHA website;
- Update the BPC on the work of RAC in relation to CLH and the PBT Expert Group;

Members were invited to remind their applicants that the ECHA Code of Conduct will be applied and applicants will need to contact the SECR on their own initiative to be invited to the meeting following the publication of agendas on the ECHA website.

7. Applications for approval of active substances

7.1 Working procedure and templates: update from SECR

7.1a New data generated after AS approval

The SECR introduced document BPC-6-2014-04 stating it will also be presented to the Coordination Group. COM stated that one process is missing as additional data for the active substance can also be submitted in an Article 95 submission. This was confirmed by SECR, although it was stated by one member that for these submissions technical equivalence is not established.

For case 1, COM stated in principle all data have to be available during the first review made for the first approval. This is even more important to avoid any issues for product authorisation. In addition, the Implementing Regulation does not include specific provisions on data requirements, so far, and there is no intention to change that practice. Following a comment from a member, the SECR explained the reasons for not including a peer review process for case 1: i) time issue as data have to be submitted ultimately 6 months before the date of approval; ii) MSCAs have the possibility to consider the data during the product authorisation process. SECR will consider including a tracking system for the submission of the data and whether R4BP could be used for it.

For case 2, several members confirmed that it is necessary to update the list of endpoints (LoEP) as soon as possible, rather than waiting for the renewal stage. COM argued on the contrary, it can be considered to update the LoEP only if the additional data are critical for the evaluation, in the light of concerns on the workload.

For case 4 several members indicated that also during the harmonised classification and labelling (CLH) process, additional data can be submitted.

With respect to section 4, the SECR clarified that one single document containing the LoEP will be made available to MSCAs and ASOs.

Actions:

- Members: to provide any further comments by 18 July in the dedicated CIRCABC newsgroup;
- SECR to make the document available for the Coordination Group Meeting in July 2014;
- SECR: to revise the document for the next meeting.

7.1b Standard phrases for active substance approval

The Chair introduced the document stating that already some comments were received on the standard phrases. Several members stated the catalogue is a useful tool for preparing draft opinions.

COM also requested that the SECR establishes a similar catalogue or a list of the reference uses assessed for each active substance/PT combination reviewed by the BPC, considering that this would help to ensure consistency in the recommendations made across the active substances assessed for the same uses. It would also help afterwards the comparative assessment and the search for alternative active substances to achieve the substitution.

Actions:

- Members: to apply the standard phrases in future draft opinions.

- SECR: to upload the catalogue to the BPC CIRCA BC after the meeting and update after each meeting, where appropriate.

7.1c Proposal for a template for BPC discussion issues on active substance applications

Members noted the proposed template (BPC-6-2014-06) and that it had been used for the current meeting. Further remarks were made in relation to the template under AOB item 11.3.

7.2 Draft BPC opinion on folpet PT 6

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 AR of folpet (PT 6) was already discussed at the BPC-5 meeting in 2014. During this discussion the AR was not agreed because major revisions were still required. As a consequence, the AR was updated following the discussion at BPC-5 and the subsequent consultation.

The revised AR and all the meeting documents were uploaded in the BPC CIRCA BC IG before the meeting. The SECR made available a note on the environmental risk assessment of folpet and a list of pre-identified issues. The rapporteur made available explanatory documents on the amendments implemented in the AR.

The Chair reported that the main changes implemented in the AR concerned the human health (AEL setting and scenarios for non-professionals) and the environmental risk assessment. The changes implemented in the AR were agreed. In addition, it was agreed that the note provided by SECR on the risk assessment for the environment will be implemented in the AR and that the confidential annex of the CAR will be updated by the eCA to address the comments received on the reference specifications. Finally, it was agreed to include in the AR a list of additional data missing for the reference product (e.g. efficacy data) and a list of additional scenarios to be considered at the product authorisation stage (e.g. additional consumption scenarios).

Concerning the revised draft opinion, in addition to editorial changes, the following were agreed to be included: a standard phrase on the need to demonstrate the efficacy of the product at the authorisation stage; and a statement concerning the eligibility for Annex I inclusion.

Members raised the issue that risks for the terrestrial compartment (soil) were identified in the case of outdoor brushing and spraying application. For the application by brushing it was agreed that risk mitigation measures were relevant. However, for spray applications the risk identified concerned the distant soil compartment, therefore, the risk mitigation measures proposed for application by brush were not considered appropriate. It was agreed to include specific conditions for approval to cover the above indicating that the labels and, where provided, safety data sheets of biocidal products authorised for the preservation of paints, films or coatings used for outdoor application by brush shall indicate measures to protect the soil to prevent losses and minimise emissions to the environment shall be taken, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means. It was also agreed to include as a condition the fact that the label (and the safety data sheets) of paints, films and coatings preserved with folpet shall indicate that they shall not be applied outdoors by spraying and that measures shall be taken to protect the soil when they are applied by brushing, unless it can be demonstrated that risks can be mitigated by other means.

With regards to the recommendations on treated articles with folpet for both PT 6 and 7, considering that knowledge and policy is under development, COM pointed out that it will study carefully the recommendations of the BPC when it proposes the corresponding draft approval regulations. The BPC adopted by consensus its opinion on an application for the approval of the active substance folpet for use in PT 6.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 31 July;
- 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 10 July and publish it on the ECHA website.

7.3 Draft BPC opinion on folpet PT 7

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.

The Chair reported that the AR of folpet (PT 7) had already been discussed at BPC-5 but had not been agreed for the reasons in 7.2 above. As a consequence the AR was updated considering the discussion at BPC-5 and the follow up consultations.

The revised AR and all the meeting documents had been uploaded in BPC CIRCA BC IG before the meeting. The SECR made available a note on the environmental risk assessment of folpet and a list of pre-identified issues. The rapporteur made available explanatory documents on the amendments implemented in the AR.

The main changes implemented in the AR concerned the human health (AEL setting and scenarios for non-professionals) and the environmental risk assessment. The changes implemented in the AR were agreed. In addition, it was agreed to implement in the AR the proposals in the note provided by SECR on the risk assessment for the environment and the confidential annex of the CAR will be updated by the eCA to address the comments received on the reference specifications. Finally, it was agreed to include in the AR a list of additional data missing for the reference product (e.g. efficacy data) and a list of additional scenarios to be considered at the product authorisation stage (e.g. additional consumption scenarios).

Once the agreement on the AR was reached, the discussion focused on the opinion. It was agreed that a statement concerning the eligibility for Annex I inclusion needs to be included in the opinion, as well as some editorial changes. The same conditions for approval agreed for folpet PT 6 were agreed for PT 7.

The main point for discussion concerned the conditions for approval of active substances to be used in treated articles. It was suggested to identify for PT 7 categories of use (e.g. infrastructure outdoor, infrastructures indoor and consumer articles excluding infrastructures) as a basis for establishing the conditions for approval for use in treated articles and to restrict the approval to the representative uses covered in the assessment performed by the eCA. COM highlighted that the general discussion already took place in CA meetings in 2013, and it was agreed that a restriction can be applied only if a major concern is identified in the assessment for the use in treated articles. It was proposed to consider including a condition indicating the need for further assessment at the product authorisation stage and that no specific conditions for approval will be included in the opinion for folpet PT 7. The BPC member from Sweden reported that due to this Sweden would like to take a minority position. The BPC adopted by simple majority its opinion on an application for the approval of the active substance folpet for use in PT 7.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 31 July;
- Member from Sweden to provide their minority position to SECR by 23 June;
- 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 10 July and publish it on the ECHA website.

7.4 Draft BPC opinion on folpet PT 9

The applicants for this active substance/PT combination remained the same as in 7.2 above and the Chair noted that the applicants had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

The Chair reported that the AR of folpet (PT 9) had already been discussed at BPC-5 but had not been agreed for the reasons in 7.2 above. As a consequence the AR was updated considering the discussion at BPC-5 and the follow up consultations.

The revised AR and all the meeting documents had been uploaded BPC CIRCA BC IG before the meeting. The SECR made available a note on the environmental risk assessment of folpet and a list of pre-identified issues. The rapporteur made available explanatory documents highlighting the amendments implemented in the AR.

The changes implemented in the AR were agreed. In addition, it was agreed to implement in the AR the proposals in the note provided by SECR on the risk assessment for the environment and that the confidential annex of the CAR will be updated by the eCA to address the comments received on the reference specifications. Finally, it was agreed to include in the AR a list of additional data missing for the reference product (e.g. efficacy data) and a list of additional scenarios to be considered at the product authorisation stage (e.g. additional consumption scenarios).

Once the agreement on the AR was reached, the discussion focused on the opinion.

It was agreed that a statement concerning the eligibility for Annex I inclusion needs to be included in the opinion. In addition, some editorial changes were agreed.

One point for discussion concerned the conditions for approval of active substances to be used in treated articles. It was proposed that the use of folpet in treated articles for PT 9 should be restricted to use in PVC. It was agreed that in the specific case of folpet no specific conditions for approval will be included in the opinion. The BPC member from Sweden therefore noted that it take a minority position for this substance/PT combination.

A member raised the issue that for one scenario risks were identified for relevant metabolites in surface water. It was clarified that the risk assessment was performed considering worst case assumptions (e.g. application of folpet to house roofs and façades and a service life of ten years); these assumptions can be refined (application of folpet only to house's roof and service life of 20 years) and this would result in no unacceptable risk. Nevertheless, it was highlighted that this scenario (PT10 - city scenario) will need to be re-assessed at the product authorisation stage.

The BPC adopted by simple majority its opinion on an application for the approval of the active substance folpet for use in PT 9. The BPC member from Sweden took a minority position.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 31 July;
- Member from Sweden to provide their minority position to SECR by 23 June;

- 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 10 July and publish it on the ECHA website.

7.5 Draft BPC opinion on carbon dioxide PT 15

The Chair informed participants that the applicant is not present for this item. There was no objection to the presence of ASOs during the discussion, and the session was therefore kept open.

The Chair reported that the CAR for carbon dioxide was discussed at the BPC Environment Working Group II 2014. The rapporteur introduced the AR and the relevant changes introduced in it, emphasising the clarification on: the use conditions and the IPM (Integrated Pest Management) strategy. Those were discussed and are described below. The AR was agreed by the BPC members with a minor modification, to include the missing list of references.

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

The eCA described the IPM (Integrated Pest Management) strategy, where, together with some preventive measures, the use of carbon dioxide is one of the approaches used to ensure the safety of air traffic at airports. The description of the IPM strategy was included in the opinion as requested.

The humaneness (no unnecessary suffering and pain for the birds) was questioned by some members and the animal welfare organisation present, who had submitted a document arguing against the use of carbon dioxide for this reason. The eCA explained that under the very specific conditions of use by trained professionals only, both efficacy and humaneness are ensured. These conditions had already been confirmed by the Efficacy Working Group.

A more clear reference to the target species, i.e. geese, was concluded to be needed in the opinion and in the requirements for product authorisation, when requested against other species than geese. Further refinements and conditions should be provided for product authorisation against other bird species.

Annex I inclusion was discussed. According to the technical criteria set out in Article 28 of the BPR, carbon dioxide could be eligible for Annex I inclusion. Nevertheless, as biocidal products containing carbon dioxide will not be eligible for the simplified procedure, due to the possible use of PPE (at certain conditions), it was concluded that Annex I inclusion would not be recommended by the BPC.

On the above basis the BPC adopted by consensus its opinion on an application for the approval of the active substance carbon dioxide for use in PT 15. One member abstained.

Several members noted that authorisations will not be granted in their Member States due to the national laws prohibiting the use of carbon dioxide to kill geese or other birds.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 31 July;
- 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 10 July and publish it on the ECHA website.

7.6 Draft BPC opinion on Alpha-cypermethrin PT 18

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 the AR and the opinion were made available in BPC CIRCA BC IG together with supporting documents from the rapporteur and the applicant.

The Chair reported that alpha-cypermethrin had already been discussed at BPC-5. The main outstanding issue concerned the consequences supporting the approval of and the possible non-compliance with the EQS (environmental quality standard) established under the Water Framework Directive (WFD)[1]. Cypermethrin is included as a priority substance in the WFD, and no distinction is made between cypermethrin and its individual isomers. This point was discussed in a recent Biocides CA meeting and the outcome of this discussion was implemented in the AR and in the opinion.

The Chair reported that at BPC-5, the BPC members were requested to provide, where available, monitoring data for alpha-cypermethrin. Only few data had been provided. One member reported that according to the monitoring data available in his country the biocidal uses of alpha-cypermethrin were not raising concerns.

The rapporteur introduced the changes that had been made in the AR and gave an overview of the principal outstanding issues related to this active substance/PT combination.

Two general points were discussed. The first issue for discussion was whether the EQS should be used instead of the derived predicted no effect concentration (PNEC) for surface water in the risk assessment. It was agreed to derive the PNEC using the data available for alpha-cypermethrin, nevertheless a justification for this decision will be included in the AR.

The need to include a dietary risk assessment was also discussed. It was agreed to consider this issue at the product authorisation stage, since this point had not been discussed at the former Technical Meeting or at a BPC Working Group. The AR was agreed with minor changes. After the agreement on the AR, the Chair introduced the draft opinion. One point for discussion concerned the appropriateness of comparing the predicted environmental concentration (PEC) with the EQS (Maximum Allowable Concentration or the annual Average). It was agreed that the comparison will be kept in the opinion, nevertheless, a sentence highlighting that this comparison may not be appropriate will be included. On this point, the conclusion of the rapporteur was endorsed and it was concluded that the fact that one of the EQS is breached by the PEC is not reason enough to prevent the approval of alpha-cypermethrin. When monitoring data for this substance are available under the WFD, these should be taken into account at product authorisation stage and if necessary, the approval of cypermethrin could be reviewed. Concerning the provision related to dietary risk assessment included in section 2.4, a member asked to delete that this assessment will be requested only if harmonised guidance is available. In fact, the dietary risk assessment shall be performed, at the product authorisation stage, with the state of the art. This was agreed.

On the above basis the BPC adopted by consensus its opinion on an application for the approval of the active substance alpha-cypermethrin for use in PT 18.

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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.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 31 July;
- 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 10 July and publish it on the ECHA website.

7.7 Draft BPC opinion on Dinotefuran PT 18

The Chair welcomed the applicant 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-6 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. A 'rev 1 version' of the AR which included minor changes that do not affect the conclusions had also been uploaded to the BPC CIRCABC IG.

The Chair reported the CAR for dinotefuran for use in PT 18 had been discussed at the BPC WG II (March 2014) and a public consultation had been performed on this substance since it was considered by the eCA to be a potential candidate for substitution.

Following the introduction of the active substance by the rapporteur the revised AR was discussed. Several changes to the AR were discussed and agreed, as the inclusion in the LoEP of the ADI (Acceptable Daily Intake) and ARfD (Acute Reference Dose) already agreed at the WG and their harmonisation with the long-term and acute AELs (Acceptable Exposure Levels), respectively. Other minor comments on the AR were agreed by the rapporteur and thus the AR was agreed. The rapporteur indicated that some editorial changes sent before the BPC were not reflected yet in the AR but would be taken into account in the final version of the AR.

After the agreement on the AR, the Chair introduced the draft opinion. It was concluded that dinotefuran is a candidate for substitution as it meets the criteria specified in Article 10(1)(d). COM proposed that the BPC provides some input concerning the alternative active substances on this issue, as the objective of the BPC is to facilitate the subsequent work at the product authorisation stage. In particular, COM considered that it would be useful to indicate in the opinion that several other active substances already approved, or reviewed by the BPC, have been evaluated for the same representative use for PT 18, listing those substances which would be potential alternatives that would need to be considered at product authorisation stage. Members considered that the name of these other substances should not yet be listed, as other potential alternatives might still be under review and further investigation needs to be performed to define if a substance is really an alternative.

The Chair concluded that a general indication of the availability of alternative active substances for the same product type will be included in Section 2.2 of the opinion.

A discussion regarding the need to include a condition on the use of dinotefuran in treated articles took place. Several proposals were considered by the BPC members and it was agreed by the majority of the members that the exclusion of the use of dinotefuran in treated articles is not appropriate, for example because this has not been assessed under the approval process as this was not applied for. Instead the following sentence was to be included in Section 2.4: "where there will be an application for product authorisation containing a use of dinotefuran in treated articles, a risk assessment should be performed for that use considering in particular its classification as very persistent (vP) and toxic (T)".

Other minor amendments to sections 2.2, 2.3 and 2.4 of the opinion were agreed. The BPC adopted by consensus its opinion on an application for the approval of the active substance dinotefuran 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 31 July;
- 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 10 July and publish it on the ECHA website.

7.8 Draft BPC opinion on triflumuron 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 triflumuron PT 18 had been discussed at the former Technical Meetings (TM I and II in 2011 and in TM II in 2012). Following the introduction of the active substance by the rapporteur Italy, the revised AR was discussed.

Following the MSCAs' comments submitted on the document, members did not agree to the proposed refinements taken in the environmental risk assessment in order to reduce the risks. For example, members doubted the practicability to comply with the requirement that manure should undergo complete aerobic composting by professionals prior to application on arable land as it is liquid manure and not dry.

One member added that risks resulting from metabolites in surface water would remain, even if the risks for the active substance are mitigated via the introduction of composting. The applicant mentioned that the metabolites are far less toxic and proposed to send in further information. The Chair replied that further data at this late stage would not be a feasible way forward in the consideration of this active substance. Due to the lack of analytical methods for transfer from food and feed such data should be required at product authorisation stage another member added.

The results of the discussions were that currently no safe use for this active substance could be identified due to the unacceptable environmental risk. However, it was noted that the spray application but not the watering can application has been assessed in the evaluation. Consequently, the BPC agreed to request the eCA to submit an assessment of the watering can use scenario and to verify if this use could lead to a safe use for the environment.

Actions:

- The rapporteur to calculate the watering can scenario and send it to the SECR by 2 September 2014;
- The SECR to schedule the discussion of the substance at BPC-7.

7.9 Draft BPC opinion on Copper pyrithione PT 21

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.

The Chair reported that copper pyrithione for PT 21 is an existing active substance submitted under the Review Programme and the eCA is Sweden. The evaluation was submitted for the peer review process before the application date of the BPR. The active

substance was discussed at several Technical Meetings (TM III 2011, TM I 2012 and TM II 2012) and at the 53rd CA meeting in September 2013. Several technical outstanding issues were also discussed at the BPC WG II 2014 for Human Health and Environment.

The rapporteur introduced the AR and the relevant changes introduced in it based on the discussions at the BPC WGs. The rapporteur also mentioned that the LoEP would be revised and the short- and medium- term dermal acceptable exposure level (AEL) value would be 0.005 mg/kg bw/day. The AR was agreed by the BPC members subject to additional minor modifications.

The BPC opinion was discussed and the key discussion points are summarised below:

In relation to the scenario of toddlers touching wet paint on a boat with and without hand-to-mouth contact, the risk was considered unacceptable and it was discussed whether the label instruction "children shall be kept away until treated surfaces are dry" could be considered a sufficient risk mitigation measure or whether the use of the substance for non-professionals should not be allowed. The rapporteur and one member pointed out that due to the acute occurrence of the effects, the proposed labelling may not be sufficient to avoid risks for toddlers and, that the effective concentration of use of copper pyrithione in antifouling products would still raise concerns, therefore the approval of the non-professional use of copper pyrithione was questioned. The majority of the BPC members were in favour of not allowing non-professional use of products containing copper pyrithione, whilst the remaining members considered the label provision a sufficient risk mitigation measure. It was therefore concluded that authorisation of products for non-professional use shall not be allowed and an 'unless clause' (stating that this cannot be allowed unless safe use is demonstrated at product authorisation) was not considered needed. Section 2.3 of the BPC opinion was to be amended accordingly.

It was agreed that it is not possible at present to conclude on the endocrine disruption properties of copper pyrithione. The table under section 2.2 was therefore to be amended accordingly.

For the use for impregnated fishnets, the environmental risk assessment could not be finalised because of the lack of available harmonised scenarios. It was agreed that this aspect should be assessed at the product authorisation stage. This will be reflected in the table "Summary table: environment scenarios" in section 2.1(c) and in section 2.4 "Elements to be taken into account when authorising products".

Other minor comments, including editorial comments, were made and were to be implemented in the BPC opinion.

It was also pointed out that the information mentioned under section 2.5 "Requirements for further information" should be submitted as soon as possible to the eCA. This will be added to this section.

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

Actions:

- The rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 31 July;
- 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 10 July and publish it on the ECHA website.

7.10 Draft BPC opinion on tolylfluanid 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 tolylfluanid had been discussed at the former Technical Meeting (TM II in 2013). Comments on the reference specifications were addressed by a member before the BPC, and it was agreed to discuss them bilaterally. The eCA was to amend the related chapter in the final version of the confidential annex of the CAR accordingly. Tolylfluanid had been approved for inclusion into the Union List of Approved Active Substances in PT 8. Following the introduction of the active substance by the rapporteur, the revised AR was discussed.

Concerning the persistency assessment, one member requested whether the metabolite DMST-acid fulfils the P criterion. The eCA replied that the only degradation data available is based on dissipation only and therefore the fulfilment of the P-criterion cannot be assessed.

The eCA reported that originally the use as an antifouling product for marine and fresh water was notified. However, the applicant wanted to withdraw the use for freshwater due to the risks of forming NDMA (N-nitrosodimethylamine) when raw water is ozonated for the preparation of drinking water. This use was however still assessed by the eCA, and unacceptable risks were identified which were therefore reflected in the assessment report.

Therefore members discussed whether the use of the active substance in products intended for use in freshwater should be restricted. The BPC agreed that tolylfluanid containing products should not be authorised for use on vessels intended to sail in freshwater. It was considered that it was not appropriate to have an “unless clause” in this case.

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 BPC adopted by consensus its opinion on an application for the approval of the active substance tolylfluanid 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 31 July;
- 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 10 July and publish it on the ECHA website.

7.11 Draft BPC opinion on Propan-2-ol PT 1

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-6 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 propan-2-ol for use in PT 1 had been discussed at the former Technical Meeting III 2013.

Following the introduction of the propan-2-ol dossier by the rapporteur the AR was presented for discussion and agreed without modifications. After the agreement on the AR, the Chair introduced the draft opinion.

Several formatting and editorial changes were agreed in the opinion. Tables, except the ones describing the scenarios for human health and environment, were to be taken out of the opinion and will be included in the section on conclusions of the AR. It was also agreed to change the wording on Section 2.4 to clarify the low expectance of residues in food and further clarifications on this point to be included in the AR. References to the aggregate risk assessment will be removed from the opinion in Sections 2.1 and 2.4, as well as Section 2.5.1 on physical and chemical properties of the product.

The BPC adopted by consensus its opinion on an application for the approval of the active substance propan-2-ol for its use in PT 1.

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 31 July;
- 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 10 July and publish it on the ECHA website.

7.12 Draft BPC opinion on Propan-2-ol PT 2

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-6 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 propan-2-ol for use in PT 2 had been discussed at the Technical Meeting III 2013.

The AR was presented for discussion and agreed without modifications. After the agreement on the AR, the Chair introduced the draft opinion. The modifications agreed for the opinion on propan-2-ol for PT 1 were also applicable to PT 2, and therefore they will be included in the opinion for PT 2.

The BPC adopted by consensus its opinion on an application for the approval of the active substance propan-2-ol for its use in PT 2.

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 31 July;
- 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 10 July and publish it on the ECHA website.

7.13 Draft BPC opinion on Propan-2-ol PT 4

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-6 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 propan-2-ol for use in PT 4 had been discussed at the Technical Meeting III 2013.

The AR was presented for discussion and agreed without modifications. After the agreement on the AR, the Chair introduced the draft opinion. The modifications agreed for the opinion on propan-2-ol for PT 1 and PT 2 were also applicable to PT 4 and therefore they were to be included in the BPC opinion for PT 4. The need of performing a dietary risk assessment was raised by several BPC members. It was agreed by the BPC that this was not necessary due to the intrinsic properties of the active substance. The eCA was to include more clarification in the AR on why residues of propan-2-ol in food are expected to be low.

The BPC adopted by consensus its opinion on an application for the approval of the active substance propan-2-ol for its use in PT 4.

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 31 July;
- 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 10 July and publish it on the ECHA website.

7.14 Draft BPC opinion on *Bacillus sphaericus* PT 18

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.

The Chair reported that the CAR for *Bacillus sphaericus* 2362 (Bs) was discussed at the TM II in 2011. The Chair noted that another microorganism *Bacillus thurigiensis isrealiensis* AM65-52 has already been included in the approved list of active substances. Following the introduction of the active substance by the rapporteur the pre-identified issues document by the SECR for *Bacillus sphaericus* and *Bacillus thurigiensis* SA3A was discussed.

The standard phrase, also used for plant protection products, to label all microorganisms as "Microorganisms may have the potential to provoke sensitising reactions" was agreed. The potential implication of the hazard statement for non-professional users was discussed. As exposure to the microorganisms and the need for potential requirement of PPE will depend on the formulation (e.g. tablet formulation in a blister) non-professional use applications were referred to product authorisation. No risks are foreseen for systemic exposure resulting from the use of the active substance, yet the potential to provoke sensitising reactions needs to be addressed.

The potential of microorganisms to provoke respiratory sensitization was briefly discussed. The lack of suitable tests was noted. The applicant added that during 30 years of use, no cases of sensitization have been reported; and referred to a bibliographic review prepared for EFSA supporting that potential respiratory sensitising effects are not foreseen. Further explanations will be given in the AR.

Further modelling of the human exposure assessment was provided by the rapporteur and will be included in the CAR and the AR.

The lack of certainty to potential expression of *Bacillus cereus* toxins by Bti SA3A shall be addressed in more detail in the AR. This is not relevant for Bs.

A member indicated that the PNEC derivation may need to be recalculated, which may have implications on the outcome of the assessment. However, it was noted that due to the limitations of the exposure assessment and lack of toxicity it is difficult to draw firm conclusions. The rapporteur concluded that no unacceptable risks are foreseen for the environment.

On request by a member the AR will be amended with further information on e-fate and the derivation of the DT50 values. A member had requested a molecular method for the identification of *Bacillus sphaericus* 2362 at strain level. It was clarified that a genomotyping study for strain identification is available and has been uploaded to CIRCA BC shortly before the BPC meeting. The member indicated that he was not aware of such a study but would check following to the BPC if the data package provided could answer to the comments raised on identity.

Reference to DE and CH guidance should be moved from 2.1.3 of the AR to a more suitable section.

The AR needs to be amended to clearly indicate the claimed and assessed uses. Also, an explanation of the basis of setting the 1 month pre-harvest interval on rice fields will need to be added.

Information on antibiotic resistance will be added to the list of endpoints. Information on genetic stability and relevance of toxins to human health will be added to the AR.

Regarding the minimum purity of microorganisms “no relevant impurities” shall be indicated. The applicant explained that it is difficult to provide application rates in both CFU/ha or IU/ha as the two units do not correlate as a result of high variability during fermentation. An explanation will be added to the AR.

Based on the discussion amendments to the opinion were proposed and agreed upon.

The applicant noted that discussions are on-going in the plant protection products area whether microorganisms can be considered as low risks substances. Nevertheless, considering that the substance was considered as provoking a sensitisation reaction, the substance was not proposed for inclusion into Annex I of BPR.

The BPC adopted by consensus its opinion on an application for the approval of the active substance *Bacillus sphaericus* 2362 for use in PT 18.

A member highlighted that the opinion was substantially revised before adoption by the BPC and that major revisions are expected in the AR as well, so as to reflect the comments raised during the meeting. The AR shall be harmonised in accordance with the opinion adopted.

Actions:

- The rapporteur to revise the AR in accordance with the discussions in the BPC and agreed comments made before the meeting and submit to the SECR by 31 July.
- The SECR to perform a quality check on the agreed amendments of the assessment report.
- 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 10 July and publish it on the ECHA website.

7.15 Draft BPC opinion on *Bacillus thurigiensis* subsp. *israelensis* SA3A PT 18

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.

The Chair reported that the CAR for *Bacillus thuringiensis subsp. israelensis* SA3A (Bti) was discussed at the TM II in 2010. The same agreements apply as for *Bacillus sphaericus* 2362 unless specifically indicated otherwise.

The BPC adopted by consensus its opinion on an application for the approval of the active substance *Bacillus thuringiensis subsp. israelensis* SA3A 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 31 July.
- The SECR to perform a quality check on the agreed amendments of the assessment report.
- 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 10 July and publish it on the ECHA website.

8. Technical equivalence and chemical similarity

8.1 Technical equivalence for multiple dossiers

The SECR introduced document BPC-6-2014-07. One member disagreed with the conclusions in the document and argued that in the case described technical equivalence has to be assessed in line with the CA guidance note indicated. This cannot be disregarded for the formal reason that it is difficult to establish the reference source. The SECR supported by several other members, clarified that the case described in the document is limited to the situation where there is more than one applicant with its own specification and complete data package. Under the condition that the provisions for the approval are the same, it is proposed in the document that this will lead to one approval and there is no need to combine these sources into one reference specification. It has to be checked if the substance is the same from the sources of the applicants, although no assessment (including for example a tier 2 assessment) of technical equivalence is required. COM emphasised that, as long as the identity of the active substance is the same, only one CA report / assessment report per AS/PT combination has to be submitted, and there shall only be one BPC opinion on an AS/PT combination. Indeed, there will be only one approval which will combine the appropriate conditions related to all dossiers, as the objective is to approve active substances and not dossiers.

Actions:

- Members to provide any further comments on the approach in the dedicated BPC CIRCA BC newsgroup by 18 July;
- SECR to revise the document for the next meeting.

9. Disinfectant by-products

The way forward presented in document BPC-6-2014-08 was generally supported. The Dutch member stated NL would like to be involved in the further development of the guidance by the proposed ad-hoc group. One member stated that PT 4 has to be included as a relevant PT for the environmental risk assessment. The member also stated that more active substances than those listed in table 1 of the document are concerned. This was confirmed by SECR, as only dossiers finalised at the former Technical Meeting are listed in this table. It was discussed whether disinfectant by-products (DBP) is an issue to be addressed at active substance approval or product authorisation stage, where the latter is indicated in the document. Several members had a preference for the active substance approval stage as it is related to the active substance and not to the product arguing that it would be disproportionate to require each applicant applying for product authorisation to address the issue of DBP. An ASO

(CEFIC) asked the SECR to consider involving relevant applicants in the further development of the guidance, and also suggested that the assessment of DBP should be considered at the renewal of the approval rather than the product authorisation stage.

Some Members suggested to analyse the possibility to have shorter period for approval, as suggested in one of the background documents. COM answered that no decision was taken on the matter.

Actions:

- Members to provide any further comments on the approach in the dedicated CIRCA BC newsgroup by 18 July and nominate participants for the ad hoc group to be established;
- SECR to consult with the NL member on the further development of the guidance by the ad hoc group.

10. Union authorisation

10.1 Product assessment report (PAR) template

The SECR presented the draft PAR template and supporting documents (BPC-6-2014-9, 10 & 11).

Several further editorial proposals for adaptations were suggested by members and these will be implemented in a revised PAR template. The BPC agreed on the PAR template with these minor modifications, but subject to consultation with the Coordination Group.

Actions:

- SECR to make the template available for the Coordination Group Meeting in July 2014;
- SECR to keep the CIRCABC newsgroup open to collect any further comments following discussion at the Coordination Group;
- SECR if possible, to finalise the template and make available on both CIRCABC and on the ECHA website, or send to the BPC for final agreement by the written procedure.

11. Any other business

11.1 Use of webex at BPC and BPC WG meetings

One member asked the SECR to clarify when Webex can be used for the participation in meetings of the BPC and the BPC WGs. The SECR agreed to clarify this at the next meeting.

11.2 Application of guidance

A member asked to clarify when new guidance would become applicable to the review of on-going applications. The Chair clarified that until now the general line is consistent with that previously agreed at Biocide Competent Authority (CA) meetings, but variations to this approach could arise in exceptional circumstances. Several members queried at what point in the process would newly agreed guidance be applicable, for example to evaluations already submitted by eCAs? The SECR agreed further clarify this and report back at the next meeting.

11.3 Review of approach to distributing substance documents

The SECR invited members to provide any comments on the process for distributing and commenting on substance documents prior to BPC meetings.

Several members noted that a complete set of documents had not been distributed for each substance before this meeting. Others pointed out the difficulty sometimes of understanding exactly what changes to the various substance documents had been agreed at the end of a BPC discussion. The SECR agreed where possible, to provide members with the full set of documents for a substance before meeting and to agree the changes to draft opinions and ARs at the meeting, after each substance discussion. In particular, a member requested to have access to the last version of the CAR before the BPC discussion, to avoid raising comments on the CAR at BPC level.

Members agreed that the discussion tables that had been distributed before this meeting had been useful, although several members noted that they anticipated the table to be focused on those outstanding issues for discussion at the meeting, rather than all of the issues noted by members, such as formatting issues. To improve the discussion flow in BPC meetings, ECHA suggested that some issues could be addressed and solved directly with the eCA, by bilateral exchanges. Several members supported this proposal.

Some members also proposed to report in the discussion tables the outcome of the BPC discussion and agreed conclusions on the identified issues.

Several members also requested bringing forward the time for distribution of these discussion tables and in turn the time for receipt of substance documents from eCAs. The Chair noted the potential difficulty this could present to eCAs, particularly given the relatively short time between the BPC WGs and the BPC meeting where a substance is discussed. Nevertheless it was agreed to further reflect on the timing. Towards meeting this objective, members were urged to ensure they provide comments on substance documents within the set deadlines.

11.4 CLH/BPR harmonisation

A member requested clarification on how Article 5(2) should be applied in practice to applications submitted after the application date of the BPR and asked for a harmonised approach. The Chair noted that this is a question of interpretation that needs further consideration at a Biocides CA meeting.

11.5 Biocides budget

The Director of Regulatory Affairs informed BPC members that a shortfall had arisen in this year's budget between the anticipated revenue and expenditure of €3.1 million. In response, ECHA together with the Commission were considering a number of options to curb the expenditure and compensate for the shortfall. The various options were to be considered over the summer and brought back for discussion at the next ECHA Management Board meeting, scheduled for September. Members were invited to keep informed of developments via their ECHA Management Board member.

11.6 Interpretation of voting provisions in the BPC Rules of Procedure

During the meeting several members queried whether they could abstain in a vote when the Committee is adopting an opinion. The SECR confirmed that the BPC Rules of Procedure can be interpreted to mean that the right to vote (Art 3(3)) implies the right to abstain from voting. Adoption by consensus (Art 19(4)) means the absence of specific opposition and therefore abstention does not affect the adoption of BPC opinions by consensus.

Actions:

The SECR to:

- Clarify when Webex can be used for participation in BPC and BPC WG (including ad hoc follow up) meetings (Item 11.1);
- Consider the line agreed at previous Biocide CA meetings on the applicability of guidance and report back at the next BPC meeting if necessary (Item 11.2);
- Where possible, to provide members with the full set of documents for a substance before meeting (Item 11.3);
- To agree the changes to draft opinions and ARs at the meeting, after each substance discussion (Item 11.3);
- Consider bringing forward the time for receipt of substance documents from eCAs and the date for distribution of these substance documents to members (Item 11.3).

Members to ensure they provide comments on substance documents within the set deadlines (Item 11.3).

SECR and COM to consult and consider at the next CA meeting the application of Article 5(2) of the BPR for submissions after the application date of the BPR (Item 11.4).

12. 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 on 19 June 2014 at the 6th meeting of BPC

16-19 June 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 items of any other business. One member requested to review the approach of the ad hoc follow-up discussions that are convened where necessary after WG meetings.	**SECR:** to upload the agreed agenda to BPC CIRCABC as part of the meeting minutes. **SECR:** agreed to review the approach for ad hoc meetings in the context of the BPC WGs.
4 - Agreement of the minutes and review of actions from BPC-5	
The revised version of the minutes of BPC-5 was agreed as proposed. One member requested an update on item 7.4 of the action points from BPC-5 in relation to PBT assessments of metabolites and impurities.	**SECR:** to upload the agreed minutes to the BPC CIRCABC and to the ECHA website after the meeting. **SECR:** to raise the issue at the next CA meeting in September 2014.
5.2 - Changes to BPC CIRCABC, the functional mailbox and other administrative issues	
It was agreed, where practicable, to bring forward by one week the date for providing the invitation and the opening of the registration for meetings. It was also agreed to maintain the two week period for registration.	**SECR:** to confirm the number of meeting days and when the invitation will be sent out.
6 - Work programme for BPC for 2014 – 2015	
It was acknowledged that the Code of Conduct for applicants will apply from BPC-7 regarding the invitation of applicants to meetings.	**SECR:** to apply from BPC-7 onwards the mechanism for engaging applicants specified in the BPC Code of conduct for applicants and highlight this on the ECHA website. **SECR:** to update the BPC on the work of RAC in relation to CLH harmonisation and the PBT Expert Group. **Members:** to remind their applicants that the ECHA Code of Conduct will be applied and applicants will need to contact the SECR on their own initiative to be invited to the meeting following the publication of agendas on the ECHA website.

7 - Applications for approval of active substances	
7.1 Working procedure and templates	
7.1a New data generated after active substance approval	**Members:** to provide any further comments on document BPC-6-2014-04 **by 18 July** in the dedicated CIRCABC newsgroup. **SECR** to make the document available for the Coordination Group Meeting in July 2014. **SECR**: to revise the document for the next meeting.
7.1b Catalogue of active substance approval conditions Document BPC-6-2014-05 was agreed.	**Members:** to apply the standard phrases in future draft opinions. **SECR:** to upload the catalogue to the BPC CIRCABC after the meeting and update after each meeting, where appropriate.
7.2 Draft BPC opinion on folpet for PT 6	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 31 July**. **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 10 July** and publish it on the ECHA website.
7.3 Draft BPC opinion on folpet for PT 7	
The BPC adopted by majority its opinion on an application for the approval of this active substance/PT combination. One member did not support the opinion.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 31 July**. **Member:** to provide their minority position to the SECR **by 23 June**. **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 10 July** and publish it on the ECHA website.
7.4 Draft BPC opinion on folpet for PT 9	
The BPC adopted by majority its opinion on an application for the approval of this active substance/PT combination. One member did not support the opinion.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 31 July**. **Member:** to provide their minority position to SECR **by 23 June**.

	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 10 July** and publish it on the ECHA website.
7.5 Draft BPC opinion on carbon dioxide for PT 15	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. One member abstained.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 31 July**. **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 10 July** and publish it on the ECHA website.
7.6 Draft BPC opinion on alpha-cypermethrin for PT 18	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 31 July**. **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 10 July** and publish it on the ECHA website.
7.7 Draft BPC opinion on dinotefuran for PT 18	
The BPC concluded dinotefuran is a candidate for substitution as it meets the criteria specified in Article 10(1)(d). The BPC adopted by consensus its opinion substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 31 July**. **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 10 July** and publish it on the ECHA website.
7.8 Draft BPC opinion on triflumuron for PT 18	
It was agreed to resume the discussion of this substance at BPC-7 after further consideration of the watering can use scenario with respect to the environmental risk assessment.	**Rapporteur:** to revise the draft opinion and the assessment report according to the discussion and submit it to the SECR **by 2 Sep**. **SECR:** to schedule the discussion of this substance for BPC-7.

7.9 Draft BPC opinion on for copper pyrithione PT 21	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 31 July**. **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 10 July** and publish it on the ECHA website.
7.10 Draft BPC opinion on for tolylfluanid PT 21	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 31 July**. **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 10 July** and publish it on the ECHA website.
7.11 Draft BPC opinion on propan-2-ol for PT 1	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 31 July**. **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 10 July** and publish it on the ECHA website.
7.12 Draft BPC opinion on propan-2-ol for PT 2	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 31 July**. **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 10 July** and publish it on the ECHA website.

7.13 Draft BPC opinion on propan-2-ol for PT 4	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 31 July**. **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 10 July** and publish it on the ECHA website.
7.14 Draft BPC opinion on *Bacillus sphaericus* for PT 18	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination.	**Rapporteur** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 31 July**. **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 10 July** and publish it on the ECHA website.
7.15 Draft BPC opinion on *Bacillus thurigiensis* SA3A for PT 18	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination.	**Rapporteur** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 31 July**. **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 10 July** and publish it on the ECHA website.
Item 8 – Establishing technical equivalence and chemical similarity	
8.1 Technical equivalence for multiple dossiers	
It was concluded that the case described in document BPC-6-2014-07 relates to the specific case of more than one applicant for the same active substance with a complete data package and their own specification. One member argued that technical equivalence is required in this specific case.	**Members:** to provide any further comments on the approach set out in document BPC-6-2014-07 in the dedicated CIRCABC newsgroup **by 18 July**. **SECR:** to revise the document for the next meeting.

Item 9 – Disinfectant by-products: a way forward	
9.1 Proposal for a way forward on disinfectant by-products for active substance approval	
The way forward presented in document BPC-6-2014-08 was generally supported, although it was discussed if it would be appropriate to apply the new guidance at product authorisation or active substance renewal.	**Members**: to provide any further comments on the approach set out in document BPC-6-2014-08 in the dedicated CIRCABC newsgroup **by 18 July** and nominate participants for the ad hoc group to be established. **SECR**: to consult with the NL member on the further development of the guidance by the ad hoc group.
Item 10 – Union authorisation	
10.1 Product assessment report (PAR) template	
The PAR template (document BPC-6-2014-10) was agreed by the BPC with minor modifications, but subject to consultation with the Coordination Group.	**SECR** to make the template available for the Coordination Group Meeting in July 2014. **SECR** to keep the CIRCABC newsgroup open to collect any further comments following discussion at the Coordination Group. **SECR** if possible, to finalise the template and make available on both CIRCABC and on the ECHA website, or send to the BPC for final agreement by the written procedure.
Item 11 – AOB	
11.1 Use of webex at BPC and BPC WG meetings	**SECR:** to clarify when webex can be used for participation in BPC and BPC WG (including ad hoc follow up) meetings.
11.2 Application of guidance	**SECR:** to consider the line agreed at previous biocides CA meetings on the applicability of guidance and report back at the next BPC meeting if necessary.
11.3 Review of approach to distributing substance documents	**SECR:** • Where possible to provide members with the full set of documents for a substance before meeting; • To agree the changes to the draft OPI and AR at the meeting, after each substance discussion; • Consider bringing forward the time for receipt of substance documents from eCAs and the date for distribution of these substance documents to members;

	Members: to provide comments by the specified deadlines.
11.4 CLH/BPR harmonisation	**SECR and COM:** to consult and consider at the next CA meeting the application of Article 5(2) of the BPR for submissions after the application date of the BPR.
11.5 Interpretation of voting provisions in the BPC RoPs The SECR confirmed that the BPC Rules of Procedure can be interpreted to mean that the right to vote (Art 3(3)) implies the right to abstain from voting. Adoption by consensus (Art 19(4)) means the absence of specific opposition and therefore abstention does not affect the adoption of BPC opinions by consensus.	

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Part III - List of Attendees

Members	Advisers
BERTAGNA Pierre-Loic (FR)	AZDAD Karima (BE)
COSTIGAN Michael (UK)	BRANDT Charlotte (BE)
CZAKÓ Klára Mária (HU)	CHEZEAU Aurelie (FR)
DONS Christian (NO)	COLLET Romy (FR)
DRAGOIU Simona (RO)	CRESTI Raffaella (IT)
GONZÁLEZ MÁRQUEZ María Luisa (ES)	GALLI Corrado (IT)
HADJIGEORGIOU Andreas (CY)	KOMEN Corine (NL)
HARRISON John (IE)	LASTBOM Lena (SE)
HEESCHE-WAGNER Kerstin (DE)	NUTI Marco (IT)
IAKOVIDOU Mary (SE)	PAASANEN Jaana (FI)
LARSEN Jørgen (DK)	PALOMAKI Jaana (FI)
MAJUS Saulius (LT)	PERSSON Johan (SE)
MERISTE Anu (EE)	PLATTNER Edmund (AT)
NELEMANS Maartje (NL)	STENHOUSE David (UK)
RUBBIANI Maristella (IT)	
SPATNY Nina (AT)	**Accredited Stakeholder Organisations**
TERNIFI Vesna (SL)	BRUYNDONCKX Raf (CEFIC)
TUUSA Tiina (FI)	OLEDZKA Gosia (AISE)
VAN BERLO Boris (BE)	REID Kirsty (Three animal welfare organisations)
ZOUNOS Athanassios (EL)	
	ECHA Staff
Alternate members	AIRAKSINEN Antero
BROVKINA Julija (LT)	BARMAZ Stefania
CHROBAK Robert (PL)	FURHMANN Anna
	HOLLINS Steve
European Commission	JANOSSY Judit
CHATELIN Ludovic	MATTHES Jochen
KILLIAN Karin	VAN DE PLASSCHE Erik

Applicants	Apologies
AZMON Adi (Adama Agricultural Solutions Ltd) for folpet PT 6, 7, and 9	ALMEIDA MARTINS Ines (PT)
BLONDAZ Pascal (Bayer S.A.S.) for Triflumuron	BUSUTTIL Ingrid (MT)
GERDES Herta (Bode Chemie GmbH) for propan-2-ol PT1, PT2, & PT4	JANTONE Anta (LT)
KANE David (LKC UK LTD) for Dinotefuran	ZIGRAND Jeff (LU)
KLICHE-SPORY Christine (LANXESS Deutschland GmbH) for Tolylfluanid	LEROY Didier (CEPE)
MUNDAY Denise (Valent BioSciences) for Bacillus sphaericus PT18; Bacillus thurigiensis SA3A PT18	
NIGGEWEG Ricarda (BASF) for alpha cypermethrin PT18	
POPPLETON Jack (Lonza) for Copper pyrithione PT21	
SCHURZ Franziska (TNO, Triskelion, Netherlands) for Copper pyrithione PT21	
Experts accompanying applicants	
HERRERO Maria (accompanying MUNDAY Denise) for Bacillus sphaericus PT18 and Bacillus thurigiensis SA3A PT18	
LICHT Oliver (accompanying GERDES Herta) for propan-2-ol PT1, PT2, & PT4	
MACKIE Carol (accompanying POPPLETON Jack) for Copper pyrithione PT21	
STRUPP Christian (accompanying AZMON Adi) for folpet PT 6, 7, and 9	

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-6 meeting

Number	**Title**
BPC-A-6-2014	Final draft agenda
BPC-M-5-2014 rev1	Draft minutes from BPC-M-5-2014_rev1
BPC/6/2014/01	Revised BPC RoPs with new declaration of interest form
BPC/6/2014/02	Revised ECHA policy on conflicts of interest
BPC/6/2014/03	BPC Work Programme 2014–2015 for active substance approvals
BPC/6/2014/04	New data generated after active substance approval
BPC/6/2014/05	Catalogue of specific provisions for active substance approval
BPC/6/2014/06	Template of BPC discussion issues for active substance approvals
BPC/6/2014/07	Technical equivalence for multiple dossiers
BPC/6/2014/08	A way forward on disinfectant by-products for active substance approval
BPC/6/2014/09	PAR template explanatory note
BPC/6/2014/10	Revised PAR template
BPC/6/2014/11	Revised PAR template, track change version

Annex II

BPC-A-6-2014 FINAL
Agreed at BPC-6
16 June 2014

Final agenda

6th meeting of the Biocidal Products Committee (BPC)

16-19 June 2014
ECHA Conference Centre, Annankatu 18, Helsinki
16 June: starts at 10:00
19 June: ends at 13:00

Item 1 – Welcome and apologies

Item 2 – Agreement of the agenda

BPC-A-6-2014
For agreement

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

Item 4 – Agreement of the minutes and review of actions from BPC-5

BPC-M-5-2014 rev1
For agreement

Item 5 – Administrative issues

5.1 Housekeeping issues

For information

5.2 Changes to CIRCA BC and functional mailbox

For information

5.3 Declaration of interest form and Rules of Procedure

BPC-6-2014-01 & 02
For information

Item 6 – Work programme for BPC for 2014 - 2015

BPC-6-2014-03

For information

Item 7 – Applications for approval of active substances

7.1 Working procedure and templates: update from SECR

a) New data generated after active substance approval

BPC-6-2014-04

For discussion

b) Proposal for a catalogue of specific conditions for active substance approval

BPC-6-2014-05

For discussion

c) Proposal for a template for BPC discussion issues on active substance applications BPC-6-2014-06

For information

7.2 Draft BPC opinion on folpet for PT 6

Previous discussion(s): BPC-5

For adoption

7.3 Draft BPC opinion on folpet for PT 7

Previous discussion(s): BPC-5

For adoption

7.4 Draft BPC opinion on folpet for PT 9

Previous discussion(s): BPC-5

For adoption

7.5 Draft BPC opinion on carbon dioxide for PT 15

Previous discussion(s): *WG-II*

For adoption

7.6 Draft BPC opinion on alpha-cypermethrin for PT 18

Previous discussion(s): BPC-5

For adoption

7.7 Draft BPC opinion on dinotefuran for PT 18

Previous discussion(s): WG-II

For adoption

7.8 Draft BPC opinion on triflumuron for PT 18

Previous discussion(s):TMIII-2011, TMII-2012

For adoption

7.9 Draft BPC opinion on for copper pyrithione PT 21

Previous discussion(s): TMIII-2011, TMI-2012, TMII-2012, CA Sept 2013, WG-II

For adoption

7.10 Draft BPC opinion on for tolylfluanid PT 21

Previous discussion(s):TMII 2013

For adoption

7.11 Draft BPC opinion on propan-2-ol for PT 1

Previous discussion(s): TMIII-2013

For adoption

7.12 Draft BPC opinion on propan-2-ol for PT 2

Previous discussion(s): TMIII-2013

For adoption

7.13 Draft BPC opinion on propan-2-ol for PT 4

Previous discussion(s): TMIII-2013

For adoption

7.14 Draft BPC opinion on Bacillus sphaericus for PT 18

Previous discussion(s):TMII-2011

For adoption

7.15 Draft BPC opinion on Bacillus thurigiensis SA3A for PT 18

Previous discussion(s): TMII-2010

For adoption

Item 8 – Establishing technical equivalence and chemical similarity

8.1 Technical equivalence for multiple dossiers

BPC-6-2014-07

For agreement

Item 9 – Disinfectant by-products: a way forward

9.1 Proposal for a way forward on disinfectant by-products for active substance approval

BPC-6-2014-08

For discussion

Item 10 – Union authorisation

10.1 Product assessment report (PAR) template

BPC-6-2014-09, 10 & 11

For agreement

Item 11 – AOB

11.1 Use of webex at BPC and BPC WG meetings

11.2 Application of guidance

11.3 Review of approach to distributing substance documents

11.4 CLH/BPR harmonisation

11.5 Biocides budget

11.6 Interpretation of voting provisions in the BPC Rules of Procedure.

Item 12 – Agreement of the action points and conclusions

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