2 February 2015

BPC-M-8-2014

Final minutes of the 8th meeting of the Biocidal Products Committee (BPC)

2 - 5 December 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 eighth BPC meeting.

The Chair informed members that the European Commission (COM) observer, Karin Kilian, will no longer participate in BPC meetings due to her new duties at COM. The Chair thanked her for her contribution to the work of BPC. The Chair announced that the German member Kerstin Heesche–Wagner and her alternate, Daniel Esch will leave the BPC by the end of the year and a new member and alternate member will be appointed. The Chair thanked the German members for their work for the Committee.

The Chair also noted that Raffaella Cresti had been appointed as the Italian alternate member.

The Chair informed BPC members of the participation of 24 members including three alternates. Owing to exceptional circumstances the Portuguese member could not attend and instead Teresa Borges was attending the meeting as an invited expert.

12 advisers, one representative from COM and two representatives from accredited stakeholder organisations (ASOs) were present at the meeting. Apologies were received from three members, and two ASO (Cefic and 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.

2. Agreement of the agenda

The Chair introduced the final draft agenda (BPC-A-8-2014 rev1) and invited any additional items. The agenda was agreed with the addition of several items under Any Other Business (see Annex II).

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 would be recorded for the purpose of the minutes and that the recording would be destroyed after the agreement of the minutes.

Seven additional meeting documents were tabled as room documents: a revised draft agenda (BPC-A-8-2014 rev 1); an additional document for cybutryne (product-type) PT 21 (BPC-8-2014-08G); a revised open issues documents for IPBC (BPC-8-2014-10C rev1) and DCCP (BPC-8-2014-12C rev1); a document for ampholyt PT 2 (BPC-8-2014-16D); two documents on PBO(BPC-8-2014-19B& C).

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

3. Declarations of potential conflicts of interest to the agenda

The 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 review of actions arising from BPC-7

The revised draft minutes from BPC-7 (BPC-M-7-2014 rev 1) were agreed taking into account the proposed changes by COM and from members. One of the members had raised a question on the minutes in relation to agenda point 7.12 MBM PT 13, namely whether standard phrases for skin sensitisation properties must be used for all active substances having these properties, for the foreseeable use patterns? The Chair confirmed that this is the intention of the catalogue, but in this case there had been a consensus that there was no possibility of skin contact under normal conditions of use from treated articles for this PT.

Under the review of actions arising from BPC-7, several points were raised in relation to the harmonised classification and labelling/persistent, bioaccumulative and toxic (CLH/PBT) overview table. One member pointed out the difficulty of assessing at what stage in the CLH process a particular dossier was at. Another member noted to clarify this aspect it could be indicated if a dossier has already been submitted to ECHA and is at the public consultation stage. COM pointed out that it would also be helpful to indicate in the table what had been included in the registry of intentions. A stakeholder observer queried how RAC (ECHA Committee for Risk Assessment) prioritises substances for consideration. The Chair agreed to make the requested changes to the table and indicated that the SECR would ask the RAC Secretariat for active substances meeting the exclusion and substitution criteria to be given priority in the CLH process.

On a separate point the Chair informed the meeting about the forthcoming workshop on increasing the effectiveness and efficiency of the active substance approval process, which ECHA will organise in the first quarter of 2015.

Actions:

- SECR to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website after the meeting;
- SECR to include in the CLH/PBT overview table:
  - The substances for which the public consultation has been launched;
  - The substances entered into the registry of intentions;
  - The planning of the RAC as is prepared by the RAC SECR for each meeting.

5. Administrative issues

5.1 Housekeeping issues

The SECR highlighted the key aspects of the housekeeping rules including the safety and security rules.

5.2 Other administrative issues

The SECR updated participants on the proposed planning for BPC-9 and indicated that given the number of substances scheduled for discussion, the meeting would need to take place over the full week (2-6 February 2015). It was pointed out that a new document had been provided for this meeting, 'Report from the other ECHA bodies' (BPC-8-2014-01). Feedback from members on the usefulness of this document was welcomed.

6. Work Programme for BPC

6.1 Revised Work Programme 2014-2015

The SECR introduced the revised BPC Work Programme (WP) for 2014 – 2015 (BPC-6-2014-20), asking members to inform the SECR of any changes. In future the Work Programme will include any changes agreed at the meeting or following week after and then this version will be published on the ECHA website and will be updated in the BPC CIRCABC. Between meetings any changes proposed by MSCAs will be included in a new working version to be discussed at the following meeting. A member informed participants that the discussion on the copper (PT 21) dossiers initially planned for the WG of March 2015 and BPC of June 2015 was withdrawn by ECHA, considering the pending WG discussion on copper PT 8 specifications. Members were asked to inform the SECR on the status and any planned submissions of CLH dossiers.

Actions:

- Members to send information on any further changes to the Work Programme to the SECR by 12 December 2014;
- SECR on the basis of the changes to update the Work Programme on the ECHA web site and in the BPC CIRCABC IG.

6.2 Outlook 2015 - 2016

The SECR provided a status overview of new active substance/PT combinations submitted under the Biocidal Products Regulation (BPR)[1]; new active substance/PT combinations submitted under the BPD; active substance/PT combinations in the Review Programme, which are not yet scheduled for BPC meetings taking place in 2015 and which belong to the first priority list due to their PTs as indicated in the Commission Delegated Regulation on the Work Programme for Active Substances[2] (PT 8, 14, 16, 18, 19 and 21); as well as Review programme: active substance/PT combinations that belong to the "back-log" dossiers. Those are active substance/PT combinations for which the evaluation had been finalised and the first draft CARs sent to COM under the old legislation.

Actions:

- Members to check the information in the tables for their active substance/PT combinations and inform the SECR of any corrections;
- Inform the SECR when their evaluations will be submitted for their active substance/PT combinations listed in the annexes to the document 'Outlook 2015-2016' by 19 December 2014;
- SECR to include the information provided and to present a revised report at BPC-9.

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

[2] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.

7. Applications for approval of active substances

7.1 Working procedure and templates: update from SECR

7.1a New data generated after active substance approval

Several members commented on case 6 ('third party dossiers') and the proposals for this case in section 3 ('submission') and 4 ('reporting'): it was noted that before agreeing on the proposed way forward in the document first more insight is needed into how ECHA performs the assessment of technical equivalence following an application under Article 54. In addition it was stated that ECHA is preparing a document on the same topic for the Coordination Group focussing more on the process and the responsibilities of ECHA and the MSCAs in the various processes of technical equivalence, the article 95 list and product authorisation. Consequently, several members required to remove case 6 from the document. There was general agreement on the proposal on the mechanism to approve significant changes in the conclusions due to the availability of new data (identification of significant change by MSCA followed by Article 15 procedure and possible request for BPC opinion under Article 75(1)(g)).

Several other comments were made on the document by several members. It was agreed to amend the document according to the BPC discussion and await the outcome of the discussion in the Coordination Group on the above mentioned ECHA document.

Actions:

- SECR to prepare a revised document for sending to the Coordination Group and to finalise the document as soon as possible afterwards.

7.1b Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval

The Chair introduced the document BPC-8-2014-04 stating that a revised version had been distributed where standard phrases for section 2.5 on requirements for further information had been added to the document. The standard condition for treated articles and skin sensitisers will refer now to only Category 1 and 1A skin sensitisers in accordance with the relevant Biocides Competent Authority Meeting note for guidance. A member noted that the latest version has not been updated according to the agreement to refer to 'protective measures' instead of 'personal protective equipment (PPE)' in a specific provision.

Actions:

- Members to apply the standard phrases in future draft opinions;
- SECR to revise and upload the catalogue to the BPC CIRCABC after the meeting.

7.1c Revision of the BPC working procedure for biocidal active substance approval

The SECR introduced the revised working procedure (BPC-8-2014-05 and Cefic comments in document 06) highlighting some of the major changes with respect to the previous version.

Several members commented on the timing of the WG meetings and the BPC meetings, which was seen as problematic because some tasks for BPC preparation take place at the same time as with the WG meetings. The time between these meetings was also considered too short, resulting in problems in delivering the updated Competent Authority Reports (CARs) for the BPC meeting and thereafter only a short time for checking and commenting on the updated CARs due to delays in providing them. One

proposal was to reduce the time for commenting on the CARs at the beginning of the peer review process. The meeting intervals and the resulting changes in the timing of other steps would be considered by the SECR, and further reflections would be possible at the workshop foreseen to be organised in early 2015 (also see item 8.2).

The need to revise CARs between the WG meetings and the BPC, especially in ways that have not been discussed at the WGs, was also seen as a problem. Possible solutions include e-consultations, ad hoc follow-ups and virtual meetings, but none of these alone were considered by the SECR to be able to solve the problem. The SECR agreed to open a newsgroup in CIRCABC dedicated to general proposals on how to deal with such issues.

The SECR will clarify the terminology regarding the old and new CAR format, and when each document is requested including the relevant timelines. The SECR also agreed to clarify the requirement for using the new CAR template and in particular will include further information on the flexibility for evaluations that are nearly finalised, that have been delayed due to missing guidance and for which a CAR is already available in another finalised product-type. It was also agreed to set a deadline (for example 90 days after the BPC meeting) for the eCA to send the final version of the CAR after the BPC opinion, in order that it is finalised before the vote on the approval/non-approval of the active substance takes place in the Standing committee (see section 8.2).

Some members requested the possibility to have a second WG discussion where necessary, but the SECR did not consider this a feasible option because of the legal obligation of finalising the opinion within 270 days.

Actions:

- Members to provide any further comments in writing by 19 December 2014 in the dedicated CIRCABC newsgroup to be established;
- SECR to prepare a revised working document for agreement at BPC-9 and include some of the wider issues at the forthcoming workshop (see item 4) in 2015.

7.1d Experience so far with respect to public consultations for potential candidates for substitution

The Chair introduced document BPC-8-2014-06 and explaining that in the public consultations to date, only very limited information had been provided on alternatives to the substances on which the consultation had been launched. Instead the public consultation had often been used by applicants to provide information on the active substance. The Chair noted that this was not the intention of this process, but nevertheless this information has to be considered by the relevant evaluating Competent Authorities (eCAs), the BPC and its Working Groups (WGs). In addition, the question was raised in the document how awareness of public consultations could be increased?

Several members and COM noted the importance of the public consultations and confirmed the need to try to reach out further to national audiences, in particular small and medium sized enterprises that comprise a large proportion of biocide companies. Members also offered to include a link from their own Member State Competent Authority (MSCA) websites to the public consultations on the ECHA website. One member also pointed out that to generate more interest in the public consultations, the SECR could provide further information about the proposed use pattern of the active substances on the ECHA website, as well as the consequences for the active substance of being targeted by exclusion or substitution. Another member suggested involving the European Environmental Bureau to investigate how producers of non-chemical alternatives to active substances could contribute to public consultations.COM underlined the importance of using the information from the public consultation when finalising BPC opinions on the approval of active substances, as requested by the BPR.

The Chair thanked participants for their contributions which would be taken into account, along with any further points in the dedicated BPC CIRCBC newsgroup for a revision of document BPC-8-2014-06 for the next meeting or at the forthcoming workshop (see item 4).

Actions:

- Members to provide any further comments in writing by 19 December 2014 in the dedicated BPC CIRCABC newsgroup to be established;
- SECR to prepare a revised document for the next meeting or for the workshop mentioned under agenda item 4.

7.2 Draft BPC opinion on *Pythium oligandrum* PT 10

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

The applicant indicated that appropriate quality control measures are in place to ensure that no toxins relevant to human health are present in the product. For clarification, the separation of non-professional and professional uses was agreed. The eCA clarified that PPE is not required when the highly diluted solution is applied by brushing and rolling. Both this scenario and the bystander scenario will be updated with a (semi)qualitative assessment comparing potential exposure through application of the diluted product and release from the wall to naturally occurring levels and to the bystander exposure resulting from the use as PPP, which was considered acceptable.

The assessment report (AR) was agreed subject to the modifications described in the open issues table. The BPC adopted by consensus its opinion on an application for the approval of *Pythium oligandrum* strain M1 for use in PT 10.

Actions:

- Rapporteur to revise the AR in accordance with the discussions in the BPC and submit to the SECR by 29 January 2015;
- 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 23 December 2014 and publish it on the ECHA website.

7.3 Draft BPC opinion on cybutryne PT 21 (closed session)

The Chair noted that the applicant had objected to the presence of ASOs during this item because confidential information was to be discussed. The session was therefore a closed session. A non-confidential summary of the discussions was provided to the ASOs at the end of the discussions.

The BPC concluded that further discussion on the environmental assessment is needed. It was agreed that four questions concerning the market share and monitoring data had to be asked to the BPC Working Group – Environment (BPC WG - ENV).

It was furthermore agreed to distribute the questions after the meeting to allow MSCAs to consider them before they are sent to the BPC WG – ENV .

Actions:

- Rapporteur with the support of the SECR to draw up a brief paper containing the four questions and explaining their background and the input required from the BPC WG – ENV by 23 January 2015;
- SECR to:

- Upload the four questions as a room document to the BPC CIRCABC IG after the meeting;
- Launch a consultation round of the BPC WG - ENV members for comments in a dedicated BPC WG CIRCABC IG newsgroup by 2 February 2015;
- Schedule the substance for discussion with the BPC WG – ENV in March 2015 with the aim of adoption at BPC-11 (June 2015).

7.4 Draft BPC opinion on hexaflumuron 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 applicant gave a brief presentation to demonstrate how termite control is carried out and the bait station used, including the tamper-proof design of the bait station.

The AR was agreed subject to the minor modifications described in the open issues table.

In the opinion, a member proposed to restrict the use to confined bait stations for termite control. It was agreed not to add this provision for consistency with previous opinions where essentiality had not been assessed, in accordance with the 'Note on the principles for taking decisions on the approval of active substances under the BPR' agreed at the 54th Biocides Competent Authority Meeting. However, it was confirmed that at the product authorisation stage a comparative assessment will be carried out as the active substance meets the substitution criteria.

The BPC adopted by consensus its opinion on an application for the approval of hexaflumuron for use in PT 18. Hexaflumuron is considered a candidate for substitution in accordance with Article 10(1)(a) of the BPR.

Actions:

- **Rapporteur**: to revise the AR in accordance with the discussions in the BPC and submit to the SECR by 29 January 2015;
- **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 23 December 2014 and publish it on the ECHA website.

7.5 Draft BPC opinion on IPBC PT 13

The Chair welcomed the applicant and the accompanying expert for this item. There was no objection to the presence of ASOs during the discussion and the session was therefore kept open.

The eCA informed participants of some editorial mistakes in the AR, which were to be modified. Other modifications were reported and unanimously agreed, without further discussion.

Several members noted that the systemic exposure assessment and risk characterisation for the use or not of gloves under different scenarios seemed to be unclear in both the AR and the opinion. As a result the following were agreed to be included in the AR: a table with the primary exposure for industrial/professional use (from Doc IIC); and an update of the local risk characterisation to consider the potential irritant/sensitising properties of IPBC when gloves cannot be worn. In the opinion, the text was to be modified to better clarify the safe use in the systemic exposure, particularly for processes where gloves are not worn and the potential risk of products containing IPBC (classified as skin sensitising category 1). The clarification that gloves are required for concentrations above 1% was also to be included.

For consistency with previous opinions on active substances in PT 13, a fourth provision was to be included in section 2.3 (specific conditions for approval) to indicate that

'loading of the products into metalworking fluids shall be semi-automated or automated, unless it can be demonstrated at product authorisation….'. Section 2.4 (elements for consideration when authorising products) was to be modified by combining elements 2 and 3 into one (on specific uses) and removing element 4 (since it is a common requirement for product authorisation).

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

Actions:

- Rapporteur to revise the AR in accordance with the discussions in the BPC and submit to the SECR by 29 January;
- 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 23 December and publish it on the ECHA website.

7.6 Draft BPC opinion on propiconazole PT 7

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

Following the introduction of the active substance by the rapporteur, the AR was presented for discussion.

A member raised the issue of the PBT assessment of the main metabolite of propiconazole (1,2,4-triazole). They proposed the degradation in soil should be recalculated at 12 °C and the toxicity assessment should be revised. The eCA agreed to revise the proposed criteria of the PBT assessment. However, it was noted that these amendments would not change the overall conclusion of the PBT assessment. The other proposed modifications to the AR were agreed by the BPC members.

In relation to the opinion, some members were in favour of maintaining the specific provision number vi under section 2.3 (BPC opinion), regarding the risks identified for the soil compartment. It was considered that a policy-related discussion was ongoing on treated articles and this specific provision had been included in the BPC opinion on other active substances. Other proposals included removing the 'unless' clause or rephrasing this provision. The proposal of rewording the provision was agreed by the BPC. It was also agreed to rewrite the specific provision number iv under section 2.3 to clarify the origin of the emission to the soil during the application of the film.

A member noted that at the product authorisation stage, there may be requests for leaching tests on mineral surfaces. In this respect, it was noted that formulations of the biocidal product intended for wooden surfaces and mineral surfaces may be different and may have a different influence on the leaching. The value of 100% was considered for leaching in the city scenario. A member suggested removing this request for a test from Section 2.4. The proposal was supported by other members, because it is additional core data (independent from formulation and use) and will anyway be requested in case of a risk at product authorisation and it was agreed to delete it.

Due to the potential application of products containing propiconazole on surfaces in contact with food, some members proposed to add a statement on the dietary risk assessment under section 2.4. Other members considered that the statement would not be relevant for propiconazole and noted that it had not been added for other PT 7 active substances. Finally, it was agreed not to include the statement on the dietary risk assessment under section 2.4.
The BPC adopted by consensus its opinion on an application for the approval of the active substance propiconazole 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 29 January;
- 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 23 December and publish it on the ECHA website.

7.7 Draft BPC opinion on DCPP PT 1

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.

The AR was agreed subject to the minor modifications.

The need for a condition for the applicant to demonstrate the benefits and efficacy of treated articles was discussed in detail. An agreement was reached that there is no legal basis to require demonstration of benefits of treated articles. The legal basis related to demonstrating efficacy of treated articles was also questioned. A member claimed that Article 58(3)(b) and also the data requirement in the efficacy section of Annex III may be applicable.

Such provisions were not made before for other actives where potential resistance in veterinary use was also an issue. A member claimed, that there had been extensive read-across for DCPP to triclosan, for which active indications suggest a potential for the development of antibiotic cross-resistance. In addition, according to efficacy tests, it may not be sufficiently effective at the product authorisation stage.

After discussion, it was agreed the boundary between what is considered a treated article and a biocidal product needs to be further clarified. Questions were also raised whether flooring or door handles in hospitals treated with a disinfectant should be considered as treated articles or biocidal products. The eCA proposed that a disinfectant should be regarded as a biocidal product when it is used with the same use pattern, for the same use and with the same indications on an article fulfilling the same criteria and being sufficiently effective to disinfect the surface. For this reason, the eCA considered the provision redundant. These aspects were to be further discussed at the Biocides Competent Authority Meeting.

The BPC adopted by consensus its opinion on an application for the approval of DCPP for the use in PT 1. DCPP is considered a candidate for substitution in accordance with Article 10(1)(d) of the BPR.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 29 January 2015;
- 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 23 December 2014 and publish it on the ECHA website.

7.8 Draft BPC opinion on DCPP PT 2

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.

For both the opinion and the assessment report the general issues related to DCPP discussed earlier are relevant for DCPP in PT 2.

The assessment report was agreed subject to the minor modifications described in the open issues table.

The BPC adopted by consensus its opinion on an application for the approval of DCPP in use of PT 2. DCPP is considered a candidate for substitution in accordance with Article 10(1)(d) of the BPR.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 29 January 2015;
- 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 23 December 2014 and publish it on the ECHA website.

7.9 Draft BPC opinion on DCPP PT 4

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.

For both the opinion and the assessment report the general issues related to DCPP discussed earlier are relevant for DCPP in PT 4.The AR was agreed subject to the minor modifications described in the open issues table.

The BPC adopted by consensus its opinion on an application for the approval of DCPP for use in PT4. DCPP is considered a candidate for substitution in accordance with Article 10(1)(d) of the BPR.

Actions:

- Rapporteur to revise the AR in accordance with the discussions in the BPC and submit to the SECR by 29 January 2015;
- 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 23 December 2014 and publish it on the ECHA website.

7.10 Draft BPC opinion on potassium sorbate PT 8

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 SECR noted that as a food additive a different acceptable daily intake had been derived than would be the case for a biocidal use alone. To ensure consistency it was agreed that further actions will be taken to harmonise with the relevant body in EFSA[3]. It was also noted by several members that contact should be strengthened between the EFSA and ECHA to ensure harmonisation of assessments between pesticides and biocides.

The AR was agreed subject to the minor modifications on presenting the classification proposal. The substance fulfils the criteria in accordance with Article 28(1) to enable inclusion in Annex I of the BPR.

[3] European Food Standards Agency.

It was agreed to clarify in the draft opinion the intended use of potassium sorbate as a wood preservative, following a request by a member.

The BPC adopted by consensus its opinion on an application for the approval of potassium sorbate for use in PT 8.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 29 January 2015;
- 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 23 December 2014 and publish it on the ECHA website;
- COM to liaise with the relevant bodies of the regulatory framework for food additives on the harmonisation of a toxicological threshold value.

7.11 Draft BPC opinion on ampholyt 20 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.

The rapporteur gave a brief introduction of the active substance, including the major concerns of the commenting members during the peer review of the opinion and the AR.

For the Human Health assessment the following issues were raised:

- The introduction of a Ready to Use (RTU) product within the draft final CAR. This use had not been followed up or agreed at the WG meeting;
- The wiping and mopping processes. Based on previous discussions on another application for the approval of an active substance (e.g. glutaraldehyde PT 2) at the BPC, it was proposed to split the processes in the assessment;
- PPE - several members considered recommending an increase of the PPE and the rapporteur had suggested PPE>90% for specialised professionals in institutional areas. It was agreed this aspect needed further clarification.

With regard to the environmental section, the following issues were raised:

- The introduction of a Ready to Use (RTU) product within the draft final CAR. This use had not been followed up or agreed at the WG meeting;
- An unacceptable risk had been identified for several compartments;
- The risk mitigation measures(RMM) were discussed, in particular whether the RMM proposed were adequate or additional RMM should be considered.

Due to the relevance of the comments received, an additional commenting period for the AR and CAR in the context of an e-consultation of the BPC WG - ENV and BPC WG – Human Health was agreed. Consequently, the adoption of the BPC opinion on ampholyt 20 PT 2 was postponed.

Actions:

- Rapporteur to prepare a document summarising the key issues for the consultation;
- SECR to coordinate the e-consultation with the BPC WGs with a view to a further discussion on a revised assessment report at a forthcoming BPC meeting;
- Rapporteur following the consultation to revise the draft opinion and assessment reports in accordance with the results of the BPC WG consultations.

7.12 Draft BPC opinion on ampholyt 20 PT 3

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 rapporteur informed the meeting that a safe used had been identified for the 'foot bath application'. For the other uses assessed, based on the comments received during the commenting round on the draft opinion, the rapporteur considered that some major changes were still needed. Therefore, it was agreed, to postpone the discussion of the opinion on ampholyt 20 PT 3 in line with the discussion for PT 2.

It was also agreed that the ongoing discussions concerning the 'foot bath scenarios' between the rapporteur and one of the commenting members could continue independent of the e-consultation proposed for the active substance.

Consequently, the adoption of the BPC opinion on ampholyt 20 PT 3 was postponed.

Actions:

- Rapporteur to prepare a document summarising the key issues for the consultation;
- SECR to coordinate the e-consultation with the BPC WGs with a view to a further discussion on a revised assessment report at a forthcoming BPC meeting;
- Rapporteur following the consultation to revise the draft opinion and assessment reports in accordance with the results of the BPC WG consultations.

7.13 Draft BPC opinion on ampholyt 20 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.

The BPC did not discuss PT 4. The action points agreed for PT 2 are applicable for this PT.

Consequently, the adoption of the BPC opinion on ampholyt 20 PT 4 was postponed.

Actions:

- Rapporteur to prepare a document summarising the key issues for the consultation;
- SECR to coordinate the e-consultation with the BPC WGs with a view to a further discussion on a revised assessment report at a forthcoming BPC meeting;
- Rapporteur following the consultation to revise the draft opinion and assessment reports in accordance with the results of the BPC WG consultations.

7.14 Consultation following the discussion on the status of piperonyl butoxide (PBO) PT 18 at the BPC Working Group – Efficacy

The Chair welcomed the applicant. There was no objection to the presence of ASOs during the discussion and the session was therefore kept open.

The rapporteur presented the view of the BPC WG – Efficacy on the status of PBO and whether it may be considered as an active substance or a synergist. The rapporteur clarified that studies demonstrating innate efficacy against dust mites and house flies had been submitted and it had been shown that PBO has its own effect against these

target organisms. Therefore PBO should be regarded as an active substance. From a regulatory point of view, the rapporteur supported PBO as an active substance since the definition of an active substance in the BPR has been modified and enlarged after the Söll case[4]. Moreover, in the plant protection product (PPP) framework, PBO is considered a synergist, since this legislation includes the definition of synergist. Therefore, to be consistent with the PPP regulation, PBO should be considered as an active substance according to the rapporteur.

The Chair then asked the Chair of the BPC WG - Efficacy to summarise the discussions that had taken place at the WG-II 2014 and WG-IV 2014 meetings. The Chair explained that during WG-II the members had access to a summary of the efficacy draft CAR and thus they had agreed that PBO is a synergist, but wished to review the results from the efficacy testing in greater detail before concluding on the efficacy of the substance. Then, the full efficacy section of the draft CAR was submitted and at the WG IV meeting the members agreed that PBO has an innate activity on its own against target organisms, also based on a study provided by the applicant close to the meeting. This conclusion had been based on the evidence provided and according to the guidance 'The role of the efficacy in the evaluation of active substance for Annex I inclusion', endorsed at 36th Biocides Competent Authority Meeting.

COM pointed out that the definitions of an active substance under the BPR and the PPP legislation are the same and that the fact that no legal definition of a synergist exists in the BPR does not automatically make such substance fall into the definition of an active substance. COM also pointed out that the PBO status had been discussed in several fora and it was agreed to consider it as a synergist pending the assessment of the eCA. If the BPC supported the conclusion that PBO should be considered an active substance, this would raise questions regarding the consistency throughout the two sets of legislation and could lead to consequences for authorised products under the BPR or national systems, products under evaluation and for prospective applicants. COM also queried how MSCAs have dealt with PBO products in the national authorisation process.

During the discussion that followed, some members pointed out the difficulty of being consistent with the PPP legislation since the definition of synergist is not included in the BPR and because the target organisms are different between biocides and PPPs. The rapporteur also highlighted that PBO should be legally treated as an active substance as notified under the Review Programme. It was recognised that MSCAs have regulated PBO in a different way at the product authorisation phase in the framework of the transitional rules for existing active substances (i.e. as a substance of concern). So far there are no biocidal products on the market containing PBO alone, since it is always used in combination with other active substances (pyrethrins and pyrethroids). It was noted that if PBO were to be considered as an active substance and approved as such, then there might be some confusion at the national authorisation level, because PBO in products on the market would be regulated as an active substance under BPR and as a synergist under the PPP legislation. The applicant confirmed that the mode of action of PBO in biocidal products or in plant protection products currently placed on the market is the same, which could also question the status under the PPP legislation.

The mode of action of PBO was also discussed and it was proposed that based on the mode of action, PBO could also be regarded as a synergist. It was indicated that PBO can be considered as an active substance because of its innate efficacy but in low doses and in combination with other active substances, then PBO should be regarded as a synergist. It was also discussed that PBO can be regarded as an active substance and synergist at the same time as it inhibits the enzymes responsible for the degradation of pyrethrins as well as the enzymes of the insects themselves.

[4] See: http://curia.europa.eu/juris/liste.jsf?language=en&num=C-420/10

The applicant clarified that PBO is regarded as an API (active pharmaceutical ingredient) by European Medicines Agency (EMA) due to its mode of action inhibiting the enzymes of insects.

The Chair concluded that the majority of the BPC members supported the conclusion of the BPC WG - Efficacy that PBO should be regarded as an active substance.

COM indicated that the wider implications of the conclusion of the BPC would be further considered at a forthcoming Biocides Competent Authority Meeting and it would liaise with the relevant bodies of the regulatory framework for pesticides.

Actions:

- COM to consider further the implications of this conclusion at the Biocides CA meeting and liaise with the relevant bodies of the regulatory framework for pesticides;
- Rapporteur to submit the draft CAR to the SECR to initiate the peer review.

8. Any other business

8.1 Changes to the opinions adopted at BPC-7 on glutaraldehyde PTs 2,3,4,6,11 and 12

The SECR explained that since their adoption at BPC-7, several technical modifications had been necessary to the opinions on the application for the approval of active substance glutaraldehyde for PTs 2,3,4,6,11 and 12. In particular, an error in the RAC opinion on glutaraldehyde had been detected after being read across to the BPC opinions. To correct this issue, the BPC opinions have been revised together with the eCA. The modifications were as below.

- In section 2.1a of the BPC opinions, in the table indicating the RAC opinion on the classification and labelling in accordance with the CLP Regulation, the row labelled 'Hazard Class and Category Codes', the classification 'STOT SE H335' has been added;
- In the same table, row 'Hazard Statement Codes', the labelling 'H335: May cause respiratory irritation' has been included.

The SECR will replace the opinions published on the ECHA website and they will be re-sent to COM.

8.2 Working approach for active substance approvals

Several questions were raised by members in relation to the working approach for active substance approvals: when should new guidance or emission scenario documents be taken into account in the peer review process; the time between BPC WG and BPC plenary meetings; and when to publish ARs.

Concerning when to use new guidance or other similar documents such as emission scenario documents, several members requested that dossiers prepared under the former legislation should not be required to comply with new guidance. Similarly, one member requested that dossiers already in the peer review process should not have to be updated if new data becomes available during the peer review process. The Chair confirmed that this aspect needs further review in order to ensure principles are established and then applied in a consistent manner and that this may be one of the items for consideration at the forthcoming workshop (see item 4).

On the timing between BPC and BPC WG meetings, several members expressed their wish to lengthen this period of time. Other members indicated that in order to work most effectively with the time available, the SECR should ensure that dossiers are not brought

forward to the BPC before they are fit for purpose for the BPC discussion. Similarly, one member noted that the number of dossiers sent back to the BPC WGs from the BPC should be minimised. In addition, several members expressed the need to further clarify the relative roles and responsibilities between the BPC, the BPC WGs and COM's Standing Committee on Biocides. In the latter case, a member requested COM and the SECR to consider further how to manage the conclusions from the Standing Committee in relation to Article 5(2) of the BPR. The Chair confirmed these requests will be considered mainly for inclusion at the forthcoming workshop.

On a related matter, several members queried whether the legal (BPR) deadline for the BPC and its WGs to deliver an opinion on applications for the approval of active substances within 270 days, applies to those substances submitted before the application date. The Chair confirmed that the agreed working approach that had been included in the BPC Working Procedure for the Approval of Active Substances was to adopt an opinion on all active substance approvals within 270 days, irrespective of whether the dossier has been submitted before or after the application date of the BPR.

A further discussion took place concerning whether ARs could be published more quickly than at present. This followed a request by one member who explained the importance of having ARs available ahead of the discussion at the Standing Committee on Biocides. The Chair pointed out that whilst this may be desirable, it was not yet possible because ARs are being submitted with confidential information in them. Several members agreed with this, although noted that the confidential information in ARs is usually limited to the list of references in the document. In the light of this information, it was agreed that in future eCAs should submit two versions of ARs to ECHA, a confidential and a non confidential version to facilitate the publication of ARs. COM re-stated its request that ARs could be published at the same time as the publication of the BPC opinion, and therefore before a decision on the approval/non-approval is adopted, as the AR reflects the technical assessment. No modification is made anymore at Standing Committee level on the AR.

It was agreed that assessment reports (ARs) shall be submitted to ECHA for the BPC discussion in a non-confidential form to allow a timely dissemination of the ARs.

Actions:

- Members to ensure two versions of the AR are submitted to ECHA after the BPC opinion is adopted: one with and one without confidential information. A non-confidential version of the AR will be submitted for the BPC discussion;
- SECR to consider dissemination of the ARs before the decision on approval;
- COM and SECR to consider further how to manage the conclusions from the Standing Committee in relation to Article 5(2);
- SECR to prepare documents for the forthcoming workshop on the basis of the discussion on the application of guidance and on the acceptance of new data during the evaluation and peer review process for active substance approval.

9. Agreement of the action points and conclusions

Part II contains the main conclusions and action points which were agreed at the meeting.

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Part II –Main conclusions and action points

Agreed on 5 December 2014 at the8th meeting of BPC

2-5December 2014

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
Item 2 - Agreement of the agenda	
The final draft agenda was agreed.	**SECR:** to upload the agreed final agenda to the BPC CIRCABC IG as part of the draft meeting minutes after the meeting.
Item 4 - Agreement of the minutes and review of actions from BPC-7	
The revised version of the minutes of BPC-7 was agreed as proposed, subject to the agreed clarification of one sentence in section 7.11. The SECR informed the meeting about the forthcoming workshop on increasing the effectiveness and efficiency of the active substance approval process, which ECHA will organise in the first quarter of 2015.	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website after the meeting. **SECR:** to include in the CLH/PBT overview table: • The substances for which the public consultation has been launched; • The substances entered into the registry of intentions; • The planning of the RAC as is prepared by the RAC SECR for each meeting.
Item 6 - Work programme for BPC for 2014 – 2015	
6.1 Revised Work Programme 2014-2015	
	Members: to send information on any further changes to the Work Programme (WP) to the SECR **by 12 December 2014**. **SECR:** on the basis of the changes to update the Work Programme on the ECHA web site and in the BPC CIRCABC IG.
6.2 Outlook (2015-16)	
The SECR provided a status overview of: • New actives submitted under the BPR; • New actives submitted under the BPD; • Review Programme: first priority list as indicated in Regulation 1062/2014 (PT 8, 14, 16, 18, 19 and 21); • Review Programme: “back-log dossiers”.	**Members** to: • Check the information in the tables for their active substance/PT combinations and inform the SECR of any corrections; • Inform the SECR when their evaluations will be submitted for their active substance/PT combinations listed in the annexes to the document ‘Outlook 2015-2016’ **by 19 December 2014**. **SECR:** to include the information provided and to present a revised report at BPC-9.

Item 7 - Applications for approval of active substances	
7.1 Working procedure and templates: update from SECR	
7.1a New data generated after active substance approval	
It was agreed to amend document BPC-8-2014-03 according to the BPC discussion and to consult the Coordination Group.	**SECR:** to prepare a revised document for sending to the Coordination Group and to finalise the document as soon as possible afterwards.
7.1b Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval	
Some comments were made on the standard phrases.	**Members:** to apply the standard phrases in future draft opinions. **SECR:** to revise and upload the catalogue to the BPC CIRCABC after the meeting.
7.1c Revision of the BPC working procedure for biocidal active substance approval	
	Members: to provide any further comments in writing **by 19 December 2014** in the dedicated CIRCABC newsgroup to be established. **SECR** agreed to clarify: • The procedure when major modifications are necessary between the WG and BPC and there is a need to consider possibilities for peer review; • The timelines for updating, finalising and publishing all documents including the final opinion and CAR/AR; • The structure of the CAR/AR and related terminology; • If the requirement for using the new CAR template can be flexible for substances where the evaluation is nearly finalised. **SECR:** to prepare a revised working document for agreement at BPC-9 and include some of the wider issues at the forthcoming workshop (see item 4) in 2015.
7.1d Experience so far with respect to public consultations for potential candidates for substitution	
	Members: to provide any further comments in writing **by 19 December 2014** in the dedicated CIRCABC newsgroup to be established. **SECR:** to prepare a revised document for the next meeting or for the workshop mentioned under agenda item 4.

7.2 Draft BPC opinion on *Pythium oligandrum* for PT 10	
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 29 January 2015**. **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 **by23 December 2014** and publish it on the ECHA website.
7.3 Draft BPC opinion on cybutryne for PT 21	
The BPC agreed on four questions concerning the market share and monitoring data to be asked to the BPC Working Group – Environment (BPC WG - ENV). It was agreed to distribute the questions after the meeting to allow MSCAs to consider them before they are sent to the ENV WG.	**Rapporteur:** with the support of the SECR to draw up a brief paper containing the four questions and explaining their background and the input required from the BPC WG – ENV **by 23 January 2015**. **SECR** to: • Upload the four questions as a room document to the BPC CIRCABC IG after the meeting; • Launch a consultation round of the BPC WG - ENV members for comments in a dedicated BPC WG CIRCABC IG newsgroup **by 2 February 2015**; • Schedule the substance for discussion with the BPC WG – ENV in March 2015 with the aim of adoption at BPC-11 (June 2015).
7.4 Draft BPC opinion on hexaflumuron for PT 18	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. The substance is considered a candidate for substitution in accordance with Article 10(1)(a) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 29 January 2015**. **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 23 December 2014** and publish it on the ECHA website.
7.5 Draft BPC opinion on IPBC for PT 13	
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 29 January 2015**. **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 **by23 December 2014** and publish it on the ECHA website.
7.6 Draft BPC opinion on propiconazole for PT 7	
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 29 January 2015**. **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 23 December 2014** and publish it on the ECHA website.
7.7 Draft BPC opinion on DCPP for PT 1	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. The substance is considered a candidate for substitution in accordance with Article 10(1)(d) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 29 January 2015**. **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 23 December 2014** and publish it on the ECHA website.
7.8 Draft BPC opinion on DCPP for PT 2	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. The substance is considered a candidate for substitution in accordance with Article 10(1)(d) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 29 January 2015**. **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 23 December 2014** and publish it on the ECHA website.
7.9 Draft BPC opinion on DCPP 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 29 January 2015**. **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 substance is considered a candidate for substitution in accordance with Article 10(1)(d) of the BPR.	**SECR:** to forward the adopted opinion to COM **by 23 December 2014** and publish it on the ECHA website.
7.10 Draft BPC opinion on potassium sorbate for PT 8	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. The substance fulfils the criteria in accordance with Article 28(1) to enable inclusion in Annex I of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 29 January 2015**. **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 23 December 2014** and publish it on the ECHA website. **Commission:** to liaise with the relevant bodies of the regulatory framework for food additives on the harmonisation of a toxicological threshold value.
7.11 Draft BPC opinion on ampholyt for PT 2, 3 and 4	
The BPC agreed to carry out an e-consultation of the BPC WGs – Human Health and Environment on the specific elements that have changed since the previous WG discussion.	**Rapporteur:** to prepare a document summarising the key issues for the consultation. **SECR:** to coordinate the e-consultation with the BPC WGs with a view to a further discussion on a revised assessment report at a forthcoming BPC meeting. **Rapporteur:** following the consultation to revise the draft opinion and assessment reports in accordance with the results of the BPC WG consultations.
7.14 Consultation following the discussion on the status of PBO PT 18 at the BPC Working Group – Efficacy	
The BPC confirmed the outcome of discussions from the BPC WG – Efficacy, namely that PBO is considered as an active substance.	**Commission:** to consider further the implications of this conclusion at the Biocides CA meeting and liaise with the relevant bodies of the regulatory framework for pesticides. **Rapporteur:** to submit the draft CAR to the SECR to initiate the peer review
Item 8 – AOB	
It was agreed that assessment reports (ARs) shall be submitted to ECHA for the BPC discussion in a non-confidential form to allow a timely dissemination of the ARs.	**Members:** to ensure two versions of the ARs submitted to the SECR, one with and one without confidential information.

	SECR to consider dissemination of the ARs before the decision on approval. **Commission and SECR:** to consider further how to manage the conclusions from the Standing Committee in relation to Article 5(2). **SECR:** to prepare documents for the forthcoming workshop on the basis of the discussion on the application of guidance and on the acceptance of new data during the evaluation and peer review process for active substance approval.

Part III - List of Attendees

Members	European Commission
BERTAGNA Pierre-Loic (FR)	CHATELIN Ludovic
COSTIGAN Michael (UK)	
CZAKÓ Klára Mária (HU)	**Advisers**
DONS Christian (NO)	AZDAD Karima (BE)
DRAGOIU Mihaela-Simona (RO)	COLLET Romy (FR)
GONZÁLEZ MÁRQUEZ María Luisa (ES)	CRESTI Raffaella (IT)
HADJIGEORGIOU Andreas (CY)	HÄMÄLÄINEN Anna-Maija (FI)
HARRISON John (IE)	JÄGER Stefanie (DE)
HEESCHE-WAGNER Kerstin (DE)	KARHI Kimmo (FI)
IAKOVIDOU Mary (SE)	KAUKONIEMI Sanna (FI)
LARSEN Jørgen (DK)	KOMEN Corine (NL)
MERISTE Anu (EE)	LÖFBOM Johanna (SE)
MIKOLASKOVA Denisa (SK)	PALOMÄKI Jaana (FI)
NELEMANS Maartje (NL)	PLATTNER Edmund (AT)
RUBBIANI Maristella (IT)	VAN GALEN Joost (NL)
TERNIFI Vesna (SL)	
TUUSA Tiina (FI)	**Accredited Stakeholder Organisations**
VAN BERLO Boris (BE)	LEROY Didier (CEPE)
VRHOVAC FILIPOVIC Ivana (HR)	REID Kirsty (Animal Welfare Organisations)
ZIGRAND Jeff (LU)	
ZOUNOS Athanassios (EL)	**Apologies**
	BUSUTTIL Ingrid (MT)
Alternate members	JANTONE Anta (LV)
CHROBAK Robert (PL)	MAJUS Saulius (LT)
KECK Marianne (AT)	BRUYNDONCKX Raf (Cefic)
MIKOLÁŠ Jan (CZ)	CAZELLE Elodie (AISE)
Invited expert	
BORGES Teresa (PT)	

Applicants	ECHA Staff
BITSCH Nikola (Celanese z.H.) for potassium sorbate PT 8	FUHRMANN Anna
CHAMP Samantha (BASF) for DCPP PT 1, 2, 4 and Cybutryne PT 21	HOLLINS Steve
CHATTON Philippe (DOW Agrosciences) for Hexaflumuron PT 18	JANOSSY Judit
FREEMANTLE Mike (IPBC Task Force) for IPBC PT 13	KENIGSWALD Hugues
KLICHE-SPORY Christine (LANXESS Deutschland GmbH) for Propiconazole PT 7	MATTHES Jochen
LEONHARDT Wolfgang (Evonik) for Ampholyt 20 PT 2, 3, 4	NEGULICI Ligia
RUBÁK Petr (Biopreparaty Spool) for *Pythium Oligandrum* PT 10	PECORINI Chiara
THOM Ellen (Endura S.p.A.) for PBO PT 18	RODRIGUEZ UNAMUNO Virginia
Experts accompanying applicants	RUGGERI Laura
GALLER Martina (accompanying FREEMANTLE Mike) for IPBC PT 13	SAEZ RIBAS Monica
HALL Caroline (accompanying LEONHARDT Wolfgang) for Ampholyt 20 PT 2, 3, 4	THUVANDER Ann
PETER Sven (accompanying CHAMP Samantha) for DCPP PT 1, 2, 4 and Cybutryne PT 21	VAN DE PLASSCHE Erik
STAVANJA Mari (accompanying BITSCH Nikola) for Potassium sorbate PT 8	

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-8 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2	BPC-A-8-2014 rev1 Room document	Draft agenda	
4	BPC-M-7-2014 rev1	Draft minutes from BPC-7	
5.2	BPC-8-2014-01	Administrative issues and report from other ECHA bodies	
6.1	BPC-8-2014-20	BPC Updated Work programme	
6.2	BPC-8-2014-02	Overview of MS active substances: new BPR, new BPD, priority deadline and backlog	
7.1a	BPC-8-2014-03	New data generated after active substance approval (AP 7.1)	
7.1b	BPC-8-2014-04	Catalogue of specific conditions and elements at the PA stage	
7.1c	BPC-8-2014-05	Revised working procedure for active substance approval	
7.1d	BPC-8-2014-06	Experience with public consultations for potential candidates for substitution	
7.1c	BPC-8-2014-21	CEFIC comments on revised working procedure for active substance approval	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.2	BPC-8-2014-07A	*Pythium oligandrum* PT 10	Draft opinion
	BPC-8-2014-07B		Assessment report
	BPC-8-2014-07C		Open issues
7.3	BPC-8-2014-08A	Cybutryne PT 21	Draft opinion
	BPC-8-2014-08B		Assessment report
	BPC-8-2014-08C		Open issues
	BPC-8-2014-08D		Position paper by BASF SE CONFIDENTIAL

	BPC-8-2014-08E		Report biocides in antifouling paint. CONFIDENTIAL
	BPC-8-2014-08F		NL CA Response to comments on draft final CAR and draft opinion of cybutryne CONFIDENTIAL
	BPC-8-2014-08G Room document		Proposed questions for the BPC WG - Environment
7.4	BPC-8-2014-09A	Hexaflumuron PT 18	Draft opinion
	BPC-8-2014-09B		Assessment report
	BPC-8-2014-09C		Open issues
7.5	BPC-8-2014-10A	IPBC PT 13	Draft opinion
	BPC-8-2014-10B		Assessment report
	BPC-8-2014-10C rev1 Room Document		Open issues
7.6	BPC-8-2014-11A	Propiconazole PT 7	Draft opinion
	BPC-8-2014-11B		Assessment report
	BPC-8-2014-11C		Open issues
7.7	BPC-8-2014-12A	DCPP PT 1	Draft opinion
	BPC-8-2014-12B		Assessment report
	BPC-8-2014-12C rev1 Room Document		Open issues
7.8	BPC-8-2014-13A	DCPP PT 2	Draft opinion
	BPC-8-2014-12B		Assessment report
	BPC-8-2014-12C rev1 Room Document		Open issues
7.9	BPC-8-2014-14A	DCPP PT 4	Draft opinion
	BPC-8-2014-12B		Assessment report
	BPC-8-2014-12C rev1 Room Document		Open issues
7.10	BPC-8-2014-15A	Potassium sorbate PT 8	Draft opinion
	BPC-8-2014-15B		Assessment report
	BPC-8-2014-15C		Open issues
7.11	BPC-8-2014-16A	Ampholyt PT 2	Draft opinion
	BPC-8-2014-16B		Assessment report
	BPC-8-2014-16C		Open issues
	BPC-8-2014-16D Room document		Evonik industry, Overview
7.12	BPC-8-2014-17A	Ampholyt PT 3	Draft opinion
	BPC-8-2014-17B		Assessment report
	BPC-8-2014-16C		Open issues

7.13	BPC-8-2014-18A	Ampholyt PT 4	Draft opinion
	BPC-8-2014-18B		Assessment report
	BPC-8-2014-16C		Open issues
7.14	BPC-8-2014-19A	PBO PT 18	Note from the Secretariat
	BPC-8-2014-19B Room document		Summary of the assessment report CONFIDENTIAL
	BPC-8-2014-19C Room document		Note from COM on PBO

Annex II

2 December 2014
BPC-A-8-2014 rev 1

Final agenda

8th meeting of the Biocidal Products Committee (BPC)

2 – 5 December ECHA Conference Centre (Annankatu 18, Helsinki)

2 December: starts at 10:00
5 December: ends at 13:00

Item 1 – Welcome and apologies

Item 2 – Agreement of the agenda

BPC-A-8-2014 rev1

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-7

BPC-M-7-2014 rev1

For agreement

Item 5 – Administrative issues

5.1 Housekeeping issues

For information

5.2 Other administrative issues

BPC-8-2014-01

For information

Item 6 – Work programme for BPC for 2014 - 2015

6.1 Revised Work Programme 2014 - 2015

BPC-8-2014-20

For information

6.2 Outlook (2015-16)

BPC-8-2014-02

For discussion

Item 7 – Applications for approval of active substances[5]

7.1 Working procedure and templates: update from SECR

a) New data generated after active substance approval

BPC-8-2014-03

For agreement

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

BPC-8-2014-04

For information

c) Revision of the BPC working procedure for biocidal active substance approval

BPC-8-2014-05 & 21

For discussion

d) Experience so far with respect to public consultations for potential candidates for substitution

BPC-8-2014-06

For discussion

7.2 Draft BPC opinion on *Pythium oligandrum* for PT 10

Previous discussion(s):TMIV-2012, BPC-7

BPC-8-2014-07A,B,C

For adoption

7.3 Draft BPC opinion on cybutryne for PT 21

Previous discussion(s): 2011 TM III, 2012 TM I

CLOSED SESSION

BPC-8-2014-08 A,B,C,D,E,F,G

For adoption

7.4 Draft BPC opinion on hexaflumuron for PT 18

Previous discussion(s): 2012 TM III, 2013 TM IV

BPC-8-2014-09A,B,C

For adoption

7.5 Draft BPC opinion on IPBC for PT 13

Previous discussion(s): 2014-WG IV

BPC-8-2014-10A,B,C rev1

For adoption

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[5] For the discussions of the draft BPC opinions at least the following documents will be distributed: a draft BPC opinion (denoted by A), a draft assessment report (may cover more than one PT and a document containing open issues (covering all the PTs to be discussed for that substance).

7.6 Draft BPC opinion on propiconazole for PT 7

Previous discussion(s): 2014 WG III

BPC-8-2014-11A,B,C

For adoption

7.7 Draft BPC opinion on DCPP PT 1

Previous discussion(s): 2013 TM IV

BPC-8-2014-12A,B,C rev1

For adoption

7.8 Draft BPC opinion on DCPP for PT 2

Previous discussion(s): 2013 TM IV

BPC-8-2014-13 A, 12B,C rev1

For adoption

7.9 Draft BPC opinion on DCPP for PT 4

Previous discussion(s): 2013 TM IV

BPC-8-2014-14 A, 12B,C rev1

For adoption

7.10 Draft BPC opinion on potassium sorbate for PT 8

Previous discussion(s): 2007 TM II, 2007 TM IV, 29th, 31st and 33rd Biocides CA meeting in 2008 and 2009

BPC-8-2014-15 A,B,C

For adoption

7.11 Draft BPC opinion on ampholyt for PT 2

Previous discussion(s): WGIII 2014

BPC-8-2014-16 A,B,C,D

For adoption

7.12 Draft BPC opinion on ampholyt for PT 3

Previous discussion(s): WGIII 2014

BPC-8-2014-17 A,B, 16C

For adoption

7.13 Draft BPC opinion on ampholyt for PT 4

Previous discussion(s): WGIII 2014

BPC-8-2014-18 A,B, 16C

For adoption

7.14 Consultation following the discussion on the status of PBO PT 18 at the BPC Working Group – Efficacy

Previous discussion(s): Efficacy WGs : *WGIII and WGIV 2014*

BPC-8-2014-19A,B,C

For agreement

Item 8 – Any other business

8.1 Changes to the opinions adopted at BPC-7 on glutaraldehyde PTs 1-6

8.2 Working approach for active substance approvals

Item 9 – Agreement of the action points and conclusions

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