

11 December 2017 BPC-M-22-2017

Minutes of the 22nd meeting of

the Biocidal Products Committee (BPC)

3-4 October 2017

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chairman of the Biocidal Products Committee (BPC) welcomed the participants to the 22nd BPC meeting and informed that within the BPC Secretariat (SECR) now Terhi Kuronen will be responsible for administrative and organisational matters and Gesine Müller will assist in scientific and technical matters.

Regarding the BPC membership, the Chairman stated that there are no changes in BPC membership but there will be one, as this is the last meeting of Corine Komen (NL). The Chairman thanked Corine for her contributions in more than 20 BPC meetings.

The Chairman then informed the BPC members of the participation of 25 members, including five alternates.

Eight advisers and one representative from accredited stakeholder organisations (ASOs) were present at the meeting. One representative from the European Commission also attended the meeting. Apologies were received from two members. One member was represented by the advisor.

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

2. Agreement of the agenda

The Chairman introduced the final draft agenda (BPC-A-22-2017_rev1) and invited then any additional items. No items were added.

The agenda was then adopted. The final version of the agenda will be uploaded to the BPC CIRCABC IG as part of the meeting minutes.

The Chairman informed the meeting participants that the meeting would be recorded for the purpose of the minutes and that the recording would be destroyed after the agreement of the minutes.

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

3. Declarations of potential conflicts of interest to the agenda

The Chairman invited BPC members, alternates and advisers to declare any potential conflict of interest in relation to the agreed agenda. None was declared.

4. Agreement of the draft minutes and review of actions arising from BPC-21

The revised draft minutes from BPC-21 (BPC-M-21-2017), incorporating the comments received from members, were agreed. SECR will check if additional data was requested for cholecalciferol and the PBT status to be reported in the revised opinion. The Chairman noted that the actions from BPC-21 have been carried out.

The Chairman informed the meeting that the first request from the Commission under Article 38 has been received on which BPC was informed. The intention is to adopt the opinion in December. A draft will be distributed by SECR this week for a commenting round. The request concerns a referral on several repellent products.

Although it was the intention of the Chairman to inform the meeting on the impact of ED assessment on the active substance approval process, it was noted that guidance notes from the Commission are still not available or agreed upon.

Actions:

• **SECR:** to upload the agreed minutes from BPC-21 to the BPC CIRCABC IG and to the ECHA website after the meeting.

5. Administrative issues

5.1 Housekeeping issues

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

5.2 Administrative updates and report from other ECHA bodies

The Chairman introduced document BPC-22-2017-01 covering the administrative updates and the report from the other ECHA Committees, provided to members for information purposes.

6. Work Programme for BPC

6.1 BPC Work Programme 2017-2018

6.2 Outlook for the BPC

The Chairman informed the members that the Work Programme was revised after the last BPC meeting and uploaded to CIRCABC. A public version was also published on the ECHA website. The document distributed for this meeting is a revised version following consultations with MSCAs based on information received following the dissemination of the previous version. Members are invited to contact the SECR on possible changes by 13 October after which a revised version will be published on the ECHA website. Some changes already received are not yet incorporated in this version.

The Chairman stated that:

- For active substance approval the foreseen opinions to be adopted for the Review Programme is now 39; total is 51. This is below the objective of 50 for the Review Programme.
- For Union authorisation it is foreseen that the first 2 opinions (for iodine/PVP-iodine in PT 3) will be adopted at the BPC in December this year. Discussions at the Working Groups took place in September and the eCA NL will submit the draft BPC opinions at the beginning of November.

The Chairman noted that with respect to active substance approval:

- almost no draft CARs were submitted in the last two process flows. This means that there are almost no draft opinions to be scheduled for the meetings next year in April and June.
- at the CA meeting last week the delays in the Review Programme focussing on the first and second priority lists were discussed. Some general causes for delays and possible solutions (mainly related to additional data during the evaluation phase, peer review and public consultation) were discussed as well as individual dossiers.

The Commission also shared ECHA's concerns on delays, which will only increase the remaining workload for the comings months and years. The Commission invited again BPC members to discuss in their authorities so that progress can be made, and proposals be discussed in the CA meetings.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) to the SECR by **13 October 2017**.
- **SECR**: on the basis of the changes to update the work programme on the ECHA website and in the BPC CIRCABC IG.

7. Applications for approval of active substances

7.1 Draft BPC opinion on chlorophene for PT 2 and 3

The Chairman welcomed the applicant for this item. The rapporteur introduced the substance and the general issues related to the active substance and the outcome of the public consultation. The assessment report (AR) and the opinions were then discussed in detail (modifications are described in the open issues table).

The BPC discussed the acceptability of double coveralls with 99% protection factor for the use of a liquid formulation containing this active substance in PT 3. The biocidal product in PT 3 would normally be used by contractors and farmers and the majority of BPC members considered that it was unrealistic that this type of PPE would be worn by farmers (and farm employees) because of discomfort during the use. In addition, it was considered that farmers (and farm employees) do not have sufficient competence to ensure that double coveralls, which is a specialised type of PPE, is used or is used correctly. Therefore,

the BPC meeting agreed that this type of PPE should not be used in the risk assessment of PT 3 substances. A safe use of chlorophene could not be identified with coveralls with a lower protection factor. Therefore non-approval was proposed for this active substance in PT 3. It was pointed out that the use of double coveralls (99% protection factor) had been accepted previously for one other active substance approval under PT3. Therefore ECHA will inform MSCAs of the BPC agreement in order to ensure consistency in product authorisations related to which type of PPE can be used and so MSCAs can take actionas appropriate with regard to products that may have already been authorised with a recommendation of use of this type of PPE.

The fulfilment of the interim criteria for endocrine disruption was noted by the BPC. The criteria stated in Article 5(3) of the BPR are currently still legally valid and should be applied until the delegated act containing the new endocrine disruption criteria has entered into force and the criteria become applicable. Therefore, the active substance is considered to meet the exclusion criteria and can only be approved in PT 2 where at least one of the conditions mentioned in Article 5(2) of the BPR is met.

A BPC member raised a general issue regarding possible restrictions on treated articles where the active substance fulfils the exclusion criteria. It was stated that for chlorophene in PT 2 this may not be relevant, as there are probably no treated articles with this active substance within PT 2. But this might differ for other active substances fulfilling exclusion criteria. It was also stated that this should be discussed at the Standing Committee for Biocidal Products, where a conclusion on the Article 5(2) derogation is made, noting that only uses where derogations is granted will be allowed.

The assessment report was agreed by the BPC. The BPC opinions on the applications for the approval of chlorophene for PT2 and 3 were adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the BPC Secretariat by **17 November 2017**.
- **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 24 October 2017 and publish it on the ECHA website.

7.2 Draft BPC opinion on azoxystrobin for PT 7, 9 and 10

The Chairman welcomed the applicant for this item. The discussion was held in closed session due to a number of issues related to the reference specification. The rapporteur introduced the substance and the general issues related to the assessment report (AR) and the opinions were then discussed in detail (modifications are described in the open issues table).

The estimation of the inhalation exposure during spray application (scenario 4) for PT 7 was discussed as many members of the HH ad hoc follow-up WG commented that the

BEAT worked example for masonry preservatives should have been used (instead of the BEAT worked example for indoor decorative painting which was chosen by the eCA). The eCA questioned the lateness of the timing of the challenge to the approach taken. However, no unacceptable risks were identified regardless of the BEAT model used. Therefore, it was agreed not to amend the AR but to add reference to the discussion that took place during the ad hoc follow-up. It was also remarked that the Guidance lists both worked examples as acceptable. The BPC agreed that revision of the current guidance document needs to clarify which is the most appropriate model to use in the future.

A lower PNEC value was derived by another MS in their assessment of azoxystrobin for another regulatory process. The new value was based on a study from public literature. The commenting member clarified that their intention was only to draw attention to this evaluation which has not yet been finalized. Therefore, it was agreed that the AR will not be amended with regard to this study and PNEC value.

It was discussed whether the preservation of mineral sealants and grouts belong to PT 7 or PT 10. It was agreed that the SECR would investigate if the preservation of mineral sealants and grouts falls under PT 7 taking into consideration consistentcy with previous evaluations and report back to the BPC.

Revision of the reference specification, identification of the relevant impurities, and the representativeness of the toxicological batches was discussed. The eCA proposed to require an Ames test to be conducted with a batch of Azoxystrobin containing representative levels of six impurities and to take no further action with regard to the impurities with QSAR alerts for skin sensitisation. SECR noted that there seems to be a need for a more generic discussion about identifying the relevant impurities, assessing the representativeness of the batches used in the (eco)toxicological tests and the consequences. Members agreed on the eCA's proposal and confirmed that they would welcome a general discussion on this topic.

It was discussed whether the intended target species should be listed in section 2.1(b) of the opinion. There were different opinions amongst members about which target species should be listed, the ones for which efficacy data was provided, i.e. efficacy was demonstrated (as it reflects on what was assessed) or the ones that the applicant claimed efficacy against. It was clarified that the Efficacy WG evaluates whether innate activity is shown for the active substance which means that the full efficacy for the representative biocidal product does not need to be demonstrated at the active substance approval stage. Therefore, there can be a difference between what the applicant applied for and what was later demonstrated to be efficacious. The BPC agreed not to list the target species in the opinion in this case.

SECR gave an update on the ECHA document on the ground water risk assessment with regard to the relevant provisions in Annex VI of the BPR that was presented to the last CA meeting. It was agreed that the text of the opinion will be modified to state whether or not the ground water trigger value is exceeded, instead of referring to the potential risk to groundwater.

Details on the public consultation will be added to the opinion. With regard to the "Requirement for further information", COM explained that the date of approval for new active substances is usually 1 year after the BPC opinion (October – November 2018 in

this case). The applicant confirmed that they will be able to submit the additional data (Ames test and analytical methods) by that deadline.

The assessment report was agreed by the BPC. The BPC opinions on the applications for the approval of azoxystrobin for PT7, 9 and 10 were adopted by majority. Germany will submit a minority position (which was later on withdrawn) as they consider that the available data is not sufficient to conclude that azoxystrobin is not genotoxic in vivo.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the BPC Secretariat by **17 November 2017**.
- **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.
- Member: to submit the minority position by **11 October 2017**.
- SECR: to forward the adopted opinion to COM by 24 October 2017 and publish it on the ECHA website.

7.3 Draft BPC opinion on PHMB (1415; 4.7) for PT 1, 2, 4, 5 and 6

The Chairman welcomed the applicant for this item. The rapporteur introduced the substance and the general issues related to the assessment report (AR). The Chairman indicated that a position paper was submitted by the applicant and commented by the rapporteur. The position paper containing the rapporteur comments was distributed as a room document. The rapporteur and the applicant introduced these documents. Thereafter, the issues, relevant for all PTs, raised in the position paper were discussed.

The first issue concerned the submission of new information during the evaluation and/or the peer review period. The Chairman highlighted that in the present case, new information was considered by the respective working groups where it was decided to take some information into account. However, the procedure as laid down in the document "Introducing new information during the peer review process of active substance approval" (agreed at BPC-13 and published on the ECHA website) was followed. This was clarified in detail for the Environment Working Group where new information was provided and considered, which involved taking into account new uses and amending non-approval proposals in some cases. More specifically, the generation of new information and how to deal with this during the review process was discussed. It appeared that new information was submitted during the 30 days commenting period according to Article 6(4) of Regulation (EU) No. 1062/2014. Several members recognized that the 30 days commenting period is not meant for the submission of additional information but to check the conclusions, to consider confidentiality and to comment on the assessment report. However, some members highlighted that the conclusion of the evaluation should not come as a surprise for the applicant especially when an approval with conditions or a nonapproval is proposed. The Commission questioned the members about their practices related to the submission of new data at a late stage in the review process and stated that the word "provide written comments" as mentioned in Article 6(4) of Regulation (EU) No. 1062/2014 is intended to review the assessment and not to submit new information. The rapporteur clarified that the applicant was not formally informed of the non-approval proposal before the 30 days commenting period. However, the rapporteur indicated that the outcome of the assessment was communicated in terms of (un)acceptable risk identified in several stages of the process. The Chairman concluded that it is clear that no new information is expected to be submitted by the applicant in the 30 days commenting period. However, there may be a need to clarify this in writing by the Commission or ECHA. This was supported by the Commission and some members. Concerning the generic issue relating to the communication between the applicant and the eCA, different practices exist in the Member States and there may be a need to reflect on this and discuss if there is a need to establish consistent good practices. For the present case, the Chairman concluded that it appears that sufficient communication has taken place between the eCA and the applicant.

The second issue concerned the read across between PHMB (1451; 4.7) and PHMB (1600; 1.8), for which the BPC already adopted opinions. It was stated by several members that the fact that the substances are not identical does not mean that read-across from one to the other is not possible. It was clarified that for toxicity via inhalation, read-across was applied to determine the reference value because the study submitted by the applicant was considered of limited reliability.

The next issue was related to the PBT assessment. The rapporteur mentioned that the case was not discussed at the PBT Expert Group because there was a clear consensus at the Environment Working Group that the substance was meeting the vP and T criteria. The current practice is that in such cases there is no need to consult the PBT Experts Group, to avoid unnecessary discussion and workload of the expert group and unnecessary delays in the review process of the substance. In addition, it was noted that the Environment Working Group has gained considerable experience and expertise in the assessment of PBT properties and that the PBT Expert Group is giving scientific advice where it is up to the Environment Working Group to decide if the PBT or vPvB criteria are met. It was agreed that this could be further clarified in the working procedure in place for the active substance approval process.

The assessment report (AR), the open-issues table and the opinions were then discussed in detail (modifications are described in the open issues table).

The Chairman confirmed that there is a need for the submission of a CLH dossier for the active substance stating that existing entry in the 9th ATP to the CLP for PHMB covers in principle both PHMB (1600; 1.8) and PHMB (1451; 4.7). The rapporteur confirmed that a CLH dossier will be submitted to ECHA taking into account the new relevant information for PHMB (1451; 4.7). The conclusion of the evaluating Competent Authority (France) is that the existing harmonized classification covers indeed also PHMB (1451; 4.7) and therefore the proposal will be made accordingly where in addition the specific identity parameters for PHMB (1451; 4.7) can be added to the entry in the ATP. It was indicated however that this argument would need to be made in the CLH dossier containing data for both PHMB (1600; 1.8) and PHMB (1451; 4.7), where it would be up to the RAC to decide.

The assessment reports for all PTs were agreed by the BPC. The BPC concluded by consensus (with the abstention of the member from CZ) that PHMB used in product-types 1, 5, 6 should not be approved. The BPC adopted by consensus the opinion for the approval of the active substance for product-types 2 and 4.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the BPC Secretariat by **17 November 2017**.
- **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 24 October 2017 and publish it on the ECHA website.

7.4 Revised Assessment Report following the submission of data after active substance approval for hydrogen peroxide for PT 1 – 6

The evaluation of the data submitted after the approval as performed by the eCA was agreed by the BPC.

Actions:

- **Rapporteur:** to revise the AR and submit it to SECR.
- **SECR:** to disseminate the revised AR on CIRCABC and on the ECHA website.

8. Union authorisation

8.1 Update on Union authorisation

An update on Union authorisation was given by the SECR to present: an overview of the current status of the applications submitted so far; an outline of the ongoing activities; and the planning for the discussions at the upcoming Working Group and BPC meetings. COM indicated that, if the grounds are legitimate and unless it is a specific case, such products may not be eligible to apply for Union authorisation in the future as it may not be considered to have similar conditions of use in the EU : discussions would have to take place at EU level on the matter. This is why it is also important that Member States comment during the pre-submission consultation so that only appropriate products enters into the UA procedure. One member stated that a chapter dealing for national derogations should be included in the template. As these national derogations are not in the scope of the BPC and are expected to only concern very few cases, it was decided to not include such a chapter in the template. If it turns out that such a chapter is needed it might be included at a later time point.

Actions:

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

8.2 Timelines for the peer review process for applications for Union authorisation

The timelines for the peer review process for applications for Union authorisation were agreed.

One member commented that physical meetings for Union authorisation would be more desirable instead of virtual meetings (as indicated in the timelines) to promote discussions and gain further expertise on the process. Such a support to physical meetings was expressed in the past also by other Member States. SECR acknowledged that physical meetings would be more beneficial, but recognised that only virtual meetings would be compatible with the fixed dates of the BPC meetings in order to accommodate the strict timelines for Union authorisation. Nonetheless, the possibility of organising physical meetings will be taken into account as much as possible, when developing the next timelines for Union authorisation.

Actions:

• **SECR:** to publish the timelines on the ECHA website.

8.3 Revised BPC opinion template for Union authorisation

The revised BPC opinion template for Union authorisation was agreed with the proposed changes.

COM reminded Member States that requests for derogation according to Article 44(5) of the BPR should be communicated to COM well in advance. Internal discussions are ongoing to define the precise timeline for submitting the requests. Moreover, COM pointed out that such requests should be properly justified, as COM will assess them. One Member State stated that a chapter dealing for national derogations should be included in the template. As these national derogations are not in the scope of the BPC and are expected to only concern very few cases, it was decided to not include such a chapter in the template. If it turns out that such a chapter is needed it might be included at a later time point.

Actions:

• **SECR:** to publish the opinion template on the BPC CIRCABC IG.

9. Article 75(1)(g) opinions

9.1 Opinion on Annex I inclusion of corn cob

The BPC postponed the adoption of the opinion on the inclusion of corn cob on Annex I to BPC-23.

Actions:

• **SECR**: to open a Newsgroup on the BPC CIRCABC IG for a one month commenting phase.

10. Any other business

10.1 Outcome of the e-consultation on open items identified at the ENV Working Group

Concerning Q1 (remits of the ENV WG when discussing RMM): it was concluded that the WG should discuss RMMs as far as they are in their area of competence with a focus on providing input on RMMs necessary and foreseen to achieve an acceptable level of risk. RMMs will be agreed by the BPC. It was further noted that awareness should be raised to the BPC where the competence of the ENV WG ended, i.e. where only limited discussion of RMMs took place.

Three items raised by BPC members during the e-consultation were further discussed:

- 1. Harmonisation applicable RMMs among MS to facility mutual recognition: BPC noted that this should take place as much as possible, the primary scope is however outside the remit of the WG.
- 2. Who should submit data on RMMs: BPC noted that the data should be provided by the applicant.
- 3. Collection of quantitative information on how RMMS reduce emissions or otherwise reduce risk: If the applicant provides quantitative information/measures, first the EFF WG should evaluate effects on efficacy. The ENV WG should evaluate the consequences on the risk assessment but only after the conclusions of the EFF WG is available (on the relevance of the proposed RMM and the implication on the dose).

Concerning Q2 (Definition of trigger values for updating the LoEP): it was concluded that an update of the LoEP should take place in general only in exceptional cases, e.g. if the new information would trigger a significant change in the outcome of the risk assessment at product authorisation level. No further triggers were proposed.

Actions:

- **COM/SECR/MS:** check procedure under PPP for updating LoEP after AS approval.
- **SECR** to report conclusions of the BPC as stated in the minutes for both questions to the ENV WG.

11. Agreement of the action points and conclusions

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

Part II - Main conclusions and action points

Agreed at the 22nd meeting of BPC

3-4 October 2017

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 <u>agreed</u> without changes.	SECR: to upload the agreed final agenda to the BPC CIRCABC IG as part of the draft meeting minutes after the meeting.	
Item 4 - Agreement of the minutes and reviev	v of actions from BPC-20	
The revised version of the minutes of BPC-21 was agreed as proposed subject to several editorial modifications.	SECR: to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website.	
Item 6 - Work programme for BPC		
6.1 Revised Work Programme 2017-20186.2 Outlook for BPC		
	Members: to send information on any further changes to the Work Programme (WP) to the SECR by 13 October 2017 .	
	SECR: on the basis of the changes to update the WP on the ECHA website and in the BPC CIRCABC IG.	
Item 7 - Applications for approval of active su	bstances	
7.1 Draft BPC opinion on chlorophene for PT	2 and 3	
The BPC <u>adopted by consensus</u> the opinions on the applications for the approval of the active substance/PT combination:	Rapporteur: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 17 November 2017 .	
 chlorophene for PT 2 should normally not be approved unless one of the conditions for derogation set in Article 5(2) of BPR is 	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.	
 met. chlorophene for PT 3 should not be approved. 	SECR: to forward the adopted opinion to COM by 24 October 2017 and publish it on the ECHA website.	
7.2 Draft BPC opinion on azoxystrobin for PT 7, 9 and 10		
The BPC <u>adopted by majority</u> the opinion for the approval of the active substance/PT combination.	Rapporteur: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 17 November 2017 .	

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	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.
	Member: to submit the minority position by 11 October 2017 .
	SECR: to forward the adopted opinion to COM by 24 October 2017 and publish it on the ECHA website.
7.3 Draft BPC opinion on PHMB (1415; 4.7) for	or PT 1, 2, 4, 5 and 6
The BPC adopted by consensus the opinion for the approval of the active substance/PT combination.	Rapporteur: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 17 November 2017 .
 PHMB for PT 2 and PT 4 should be approved. 	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.
 PHMB for PT 1, PT 5 and PT 6 should not be approved. 	SECR: to forward the adopted opinion to COM by 24 October 2017 and publish it on the ECHA website
7.4 Revised Assessment Report following the approval for hydrogen peroxide for PT 1 - 6	submission of data after active substance
The BPC agreed to evaluation of the eCA of the data received after the approval of hydrogen	Rapporteur: to revise the AR and submit it to SECR.
peroxide for PT 1 – 6.	SECR: to disseminate the revised AR on CIRCABC and on the ECHA website.
Item 8 – Union authorisation	
8.1 Update on Union authorisation	
The meeting was informed about the developments on Union authorisation.	SECR: to upload the presentation on the BPC CIRCABC IG.
8.2 Timelines for the peer review process for	applications for Union authorisation
The timelines for the peer review process for applications for Union authorisation were agreed.	SECR: to publish the timelines on the ECHA website.
8.3 Revised BPC opinion template for Union a	authorisation
The template for the opinion for Union authorisation was agreed.	SECR: to publish the opinion template on the BPC CIRCABC IG.
Item 9 – Article 75(1)(g) opinions	
9.1 Opinion on Annex I inclusion of corn cob	

Item 10 – AOB		
The BPC postponed the adoption of the opinion on the inclusion of corn cob on Annex I to BPC- 23.	SECR: to open a Newsgroup on the BPC CIRCABC IG for a one month commenting phase.	

10.1. Outcome of the e-consultation on open items identified at the ENV Working Group	
Q1: ENV WG should discuss RMMs as far as in their area of competence. Conclusions on RMM are in the remit of the BPC.	COM/ECHA/MS: check procedure under PPP for updating LoEP after first approval.
Q2: LoEP should be updated only in exceptional cases (e.g. if significant change in risk assessment are triggered).	

Members	European Commission
BORGES Teresa (PT)	CHATELIN Ludovic (DG SANTE)
BROVKINA Julija (LV)	
BROWN Finbar (IE)	Advisers
CABALLO DIÉGUEZ Covadonga (ES)	AAMODT Solveig (NO)
COSTIGAN Michael (UK)	BOITIER Caroline (FR)
DRAGOIU Simona (RO)	GOURLAY-FRANCÉ Catherine (FR)
GIORDMAINA Wayne (MT)	HÄMÄLÄINEN Anna-Maija (FI)
GORDON Suzanne Collett (NO)	HAUGSTAD Kjetil (NO)
HADAM Anna (PL)	KALKERS Lucas (NL)
HAHLBECK Edda (SE)	KARHI Kimmo (FI)
JOHN Nina (AT)	WEINHEIMER Viola (DE)
JÄGER Stefanie (DE)	
KOIVISTO Sanna (FI)	
KOMEN Corine (NL)	Accredited Stakeholder Observers
LARSEN Jørgen (DK)	MONTMOREAU Bertrand (CEPA)
MERISTE Anu (EE)	
VAN BERLO Boris (BE)	
VRHOVAC FILIPOVIC Ivana (HR)	ECHA Staff
ZIGRAND Jeff (LU)	AIRAKSINEN Antero
ZOUNOS Athanassios (EL)	ESTEVAN MARTINEZ Carmen
	KURONEN Terhi
Alternate members	MULLER Gesine
ALEXANDROS Gavriel (CY)	PECORINI Chiara
CRESTI Raffaella (IT)	RODRIGUEZ UNAMUNO Virginia
MIKOLÃS Jan (CZ)	SCHIMMELPFENNIG Heike
PYTHON François (CH)	VAN DE PLASSCHE Erik
SZENTGYÖRGYI Timea Ilona (HU)	

Part III - List of Attendees

Applicants	Apologies
KLICHE-SPORY Christine (LANXESS Deutschland GmbH) for chlorophene for PT 2 and 3	CEBAŠEK Petra (SI)
SAUER Frank (LANXESS Deutschland GmbH) for azoxystrobin for PT 7, 9 and 10	MIKOLASKOVA Denisa (SK)
CROS Daniel (Laboratoire PAREVA) for PHMB (1415; 4.7) for PT 1, 2, 4, 5 and 6	
Experts accompanying applicants	
SCARROTT Simon, accompanying SAUER Frank, for azoxystrobin for PT 7, 9 and 10	
VAN MALDEGEM Koen, accompanying CROS Daniel, for PHMB (1415; 4.7) for PT 1, 2, 4, 5 and 6	

Part IV - List of Annexes

- Annex I List of documents submitted to the members of the Biocidal Products Committee
- Annex II Final agenda of BPC-22

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-22 meeting

Meeting documents				
Agenda Point	Number	Title		
2	BPC-A-22-2017	Draft agenda		
4	BPC-M-21-2017	Draft minutes from BPC-2	Draft minutes from BPC-20	
5.2	BPC-22-2017-01	Administrative issues and	Administrative issues and report from the other Committees	
6.1	BPC-22-2017-02	BPC updated Work Progra	amme 2017-2018	
6.2	BPC-22-2017-03	Outlook for the BPC		
7.4	BPC-22-2017-15	Revised Assessment Report following the submission of data after active substance approval for hydrogen peroxide for PT 1 - 6		
8.1	BPC-22-2017-16	Update on Union authoris	sation	
8.2	BPC-22-2017-17	Timelines for the peer review process for applications for UA		
8.3	BPC-22-2017-18	Revised BPC opinion template for UA		
9.1	BPC-22-2017-14	Opinion on Annex I inclusion of corn cob		
10.1	BPC-22-2017-19	Outcome of the e-consultation on open items identified at the ENV Working Group		
Substance documents				
Agenda Point	Number	Substance-PT	Title	
	BPC-22-2017-04A	Chlorophene PT 2	Draft BPC opinion	
	BPC-22-2017-04B		Assessment report	
7.1	BPC-22-2017-04C		Open issues	
	BPC-22-2017-05A	Chlorophene PT 3	Draft BPC opinion	
	BPC-22-2017-05B		Assessment report	
	BPC-22-2017-04C		Open issues	
	BPC-22-2017-06A		Draft BPC opinion	
7.2	BPC-22-2017-06B	Azoxystrobin PT 7	Assessment report	

	BPC-22-2017-06C		Open issues
	BPC-22-2017-07A	Azoxystrobin PT 9	Draft BPC opinion
	BPC-22-2017-07B		Assessment report
	BPC-22-2017-06C	Open issues	
	BPC-22-2017-08A		Draft BPC opinion
	BPC-22-2017-08B	Azoxystrobin PT 10	Assessment report
	BPC-22-2017-06C	_	Open issues
	BPC-22-2017-09A		Draft BPC opinion
	BPC-22-2017-09B	PHMB (1415; 4.7) PT 1	Assessment report
	BPC-22-2017-09C		Open issues
	BPC-22-2017-10A	PHMB (1415; 4.7) PT 2	Draft BPC opinion
	BPC-22-2017-10B		Assessment report
	BPC-22-2017-09C		Open issues
	BPC-22-2017-11A	PHMB (1415; 4.7) PT 4	Draft BPC opinion
7.3	BPC-22-2017-11B		Assessment report
	BPC-22-2017-09C		Open issues
	BPC-22-2017-12A	PHMB (1415; 4.7) PT 5	Draft BPC opinion
	BPC-22-2017-12B		Assessment report
	BPC-22-2017-09C		Open issues
	BPC-22-2017-13A	PHMB (1415; 4.7) PT 6	Draft BPC opinion
	BPC-22-2017-13B		Assessment report
	BPC-22-2017-09C		Open issues



20 September 2017 BPC-A-22-2017_rev1

Draft agenda

22nd meeting of the Biocidal Products Committee (BPC) 3 – 4 October 2017 ECHA Conference Centre, Annankatu 18, Helsinki

Starts on 3 October at 09:30, ends on 4 October at 16:00

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-22-2017_rev1 For agreement

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

4. – Agreement of the minutes and review of actions from BPC-21

BPC-M-21-2017 For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

BPC-22-2017-01 *For information*

6. – Work programme for BPC

6.1. Revised BPC Work Programme 2017-2018 BPC-22-2017-02 For information 6.2. Outlook for BPC BPC-22-2017-03 For information

7. – Applications for approval of active substances*

7.1. Draft BPC opinion on chlorophene for PT 2 and 3 *Previous discussion(s): WG-III-2017*

PT 2: BPC-22-2017-04A, B and C

PT 3: BPC-22-2017-05A, B and BPC-22-2017-04C For adoption

7.2. Draft BPC opinion on azoxystrobin for PT 7, 9 and 10 *Previous discussion(s): WG-III-2017*

PT 7: BPC-22-2017-06A, B and C
PT 9: BPC-22-2017-07A, B and BPC-22-2017-06C
PT 10: BPC-22-2017-08A, B and BPC-22-2017-06C *For adoption*

7.3. Draft BPC opinion on PHMB (1415; 4.7) for PT 1, 2, 4, 5 and 6 *Previous discussion(s): WG-III-2017*

PT 1: BPC-22-2017-09A, B and C
PT 2: BPC-22-2017-10A, B and BPC-22-2017-09C
PT 4: BPC-22-2017-11A, B and BPC-22-2017-09C
PT 5: BPC-22-2017-12A, B and BPC-22-2017-09C
PT 6: BPC-22-2017-13A, B and BPC-22-2017-09C

For adoption

7.4. Revised Assessment Report following the submission of data after active substance approval for hydrogen peroxide for PT 1 - 6

BPC-22-2017-15 For agreement

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

Item 8 – Union authorisation

8.1 Update on Union authorisation

BPC-22-2017-16 For information

8.2 Timelines for the peer review process for applications for Union authorisation

BPC-22-2017-17 For agreement

8.3 Revised BPC opinion template for Union authorisation

BPC-22-2017-18 *For agreement*

Item 9 – Article 75(1)(g) opinions

9.1 Opinion on Annex I inclusion of corn cob

BPC-22-2017-14 For adoption

Item 10 – Any other business

10.1. Outcome of the e-consultation on open items identified at the ENV Working Group

BPC-22-2017-19 For agreement

Item 11 – Agreement of the action points and conclusions

For agreement



Provisional timeline for the 22st meeting of the Biocidal Products Committee (BPC) ECHA Conference Centre, Annankatu 18, Helsinki 3 October 2017: starts at 09:30; 4 October ends at 16:00

Please note that the timings indicated below are provisional and subject to possible change. They are distributed to participants on a preliminary basis.

Tuesday 3 October: morning session

- Items 1-5 Opening items and administrative issues
- Item 6 Work programme of the BPC 2017-18
- Item 7.1 Draft BPC opinion on chlorophene for PT 2 and 3

Tuesday 3 October: afternoon session

Item 7.2 Draft BPC opinion on azoxystrobin for PT 7, 9 and 10

Wednesday 4 October: morning session

Item 7.3 Draft BPC opinion on PHMB (1415; 4.7) for PT 1, 2, 4, 5 and 6

Wednesday 4 October: afternoon session

Item 7.4	Revised Assessment Report following the submission of data after active substance approval for hydrogen peroxide for PT 1 - 6 $$
Item 8.1	Update on Union authorisation
Item 8.2	Timelines for the peer review process for applications for Union authorisation
Item 8.3	Revised BPC opinion template for Union authorisation
Item 9.1	Opinion on Annex I inclusion of corn cob
Item 10.1	Outcome of the e-consultation on open items identified at the \ensuremath{ENV} Working Group
Item 11	Agreement of action points and conclusions

End of meeting

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