2 March 2021

BPC-M-37-2020

Minutes of the 37th meeting of the Biocidal Products Committee (BPC)

1-4 December 2020

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chair of the Biocidal Products Committee (BPC) welcomed the participants to the 37th BPC meeting which took place as a fully virtual meeting via Webex.

Regarding the BPC membership, the Chair stated that there is a new appointed BPC member from Hungary: Timea Szentgyorgyi and a new appointed alternate BPC member also from Hungary: Henrietta Szabo.

The Chair then informed the BPC members of the participation of 26 members, including five alternate members. In addition, Poland was represented by an invited expert.

24 advisers and 5 representatives from an accredited stakeholder organisation (ASO) were present at the meeting. Five representatives from the European Commission attended the meeting.

Applicants were invited and present for their specific substances under agenda item 7 and biocidal products under agenda item 8, 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 Chair introduced the final draft agenda (BPC-A-37-2020_rev1) and invited any additional items. No additional items were presented and the agenda was adopted. The final version of the agenda will be uploaded to the BPC CIRCABC IG as part of the meeting minutes.

The Chair informed the meeting participants that the meeting would be recorded for the purpose of the minutes and that the recording would be deleted 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 Chair 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-36

The revised draft minutes from BPC-36 (BPC-M-36-2020), incorporating the comments received, were agreed.

The Chair noted that all actions from BPC-36 have been carried out.

The Chair further informed the meeting on the following:

- Opinions on active chlorine released from hypochlorous acid: after the meeting the opinions were finalised and published. However, a mistake was identified thereafter on the statement of the chlorate content. ECHA consulted with the eCA SK on the issue. The revised opinions have now been disseminated on the ECHA web-page containing a higher concentration of sodium chlorate compared to the "older version". This value is also indicated in section 2.3 as sodium chlorate is a relevant impurity.
- Regarding "Listing of precautionary statements in section 3 and 5.3 of the SPC" (agenda item 8.1 of BPC-35): the Coordination Group (CG) discussed the issue at its last meeting and agreed on the proposal from FR. The guidance has now been published and is relevant for national and Union authorisation.
- The CG finalised the guidance on first aid instructions based on a proposal from SE. The guidance has now been published and is relevant for national and Union authorisation.
- Concerning the court case on the non-approval decisions for some applications for PHMB: the hearing on this case took place in the EU Court of Justice. Relevant for the BPC is that the Court of Justice expressed some criticism on the BPC opinion forming the basis for the decision: it appeared that it was not clear in the opinion which critical effect formed the basis for the human health risk assessment. The Chair stated that due to this case there is a need to improve the BPC opinions in terms of providing more information on this aspect. The SECR will come with a proposal for the next meeting.
- Post approval data: the Chairman asked the member from IE if he can inform if Ampholyt 20 can be discussed at the next BPC meeting.

Actions:

- **SECR:** to upload the agreed minutes from BPC-36 to the BPC S-CIRCABC IG and to the ECHA website after the meeting.

5. Administrative issues

5.1 Pre-announcement new functionalities in the Interact portal

A presentation on new functionalities in the Interact portal was given by the SECR.

5.2 Feedback received by SECR via questionnaire on virtual meeting in October

The Chair presented the summary of the feedback received on the virtual BPC-36 meeting in October.

6. Work Programme for BPC

6.1. BPC Work Programmes for active substance approval, Union authorisation, ED assessment and outlook for BPC

The Chair informed members that the Work Programme for active substance approval was revised after the last BPC meeting. Members were invited to contact the SECR on possible changes on the revised programme after which an updated version will be published on the ECHA website.

The Chair stated that:

- For active substance approval 15 opinions are scheduled to be adopted this year, all for the Review Programme. Also 10 opinions have been adopted for the Review Programme being returned opinions via an Article 75(1)(g) for ED assessment.
- For Union authorisation the number of opinions to be adopted this year is 10, which is the same as in 2019.
- Furthermore 2 opinions following an Article 75(1)(g) request are adopted bringing the total of number of opinions together with the one on the renewal of creosote for PT 8, to 38 which is almost twice as much as in 2019.
- Reference was made to the discussions at the CA meeting in December where ECHA will present an overview of dossiers for active substance approval and renewal of approval and applications for Union authorisation planned by the Member States for the coming years and an overview of the status on the ED assessment.
- Reference was made to the status of ED assessment for information purposes. Compared to the last version tabled for BPC-36: i) the information on the EDEG is updated (IBPC discussed in the October EDEG meeting) and a column is added on how many active substances are remaining since April 2018, when the first of the two Article 75(1)(g) requests was received: 10 (was 21) active substances for 23 PTs (was 47) remain at this moment. The Chair mentioned that there is no decision from the CA meeting yet on whether an ED assessment is required if the active substance is already meeting the exclusion criteria. However, the Commission added that as baseline, an ED assessment was always required, also for active substances already fulfilling exclusion criteria. Only in very exceptionally cases, the lack of an ED assessment can be accepted.

The Chair asked the eCAs being rapporteur for active substances or Union authorisations scheduled for discussion at the March 2021 BPC meeting (BPC-38), to confirm this planning to the SECR by 18 January 2021.

Similarly to previous meetings, the Commission expressed concerns on the general progress which is still insufficient to conclude the review programme by 2024 and reminded that Member States must implement the actions agreed at the CA meeting and in the ECHA Action plan, in particular to deliver the draft assessment reports and to not postpone discussions on their substances from BPC meeting to meeting. Progress must also be made on backlog reports submitted before 1 September 2013 for which decisions must still be based under BPD principles. The Commission also reminded that, as regards to the need to perform an ED assessment when the substance is already meeting the exclusion criteria, the current position is that an ED assessment is needed, but it is still investigating whether there could be possibities to move forwards without such assessment.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by **11 December 2020**.

7. Applications for approval of active substances

7.1. Procedural and administrative aspects:

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

The Chair stated the changes introduced in the document.

Actions:

- **Members:** To check the standard conditions when preparing opinions.

7.2. Draft BPC opinion on the renewal of creosote for PT 8

The Chair welcomed the applicant. The stakeholders were allowed to be present during the discussion. This was the second BPC discussion on the renewal of creosote in PT8. The discussion was divided over two days; in the first session the items in the open issues table were discussed and the second session was dedicated to the amendments on the draft opinion according to the discussions during the first session.

Remaining issues on the Renewal Assessment Report

After the previous discussion at BPC-36 the rapporteur had made major revisions to the Renewal Assessment Report (RAR), mainly related to the T25 derivation and the assessment for the brushing application. In this regard, an ad hoc Human Health Working Group (HH WG) meeting took place on 19 October 2020 where the revision of the T25 value was discussed. The relevant sections of the RAR were consequently revised based on the agreed T25 value. The applicant expressed their disagreement to the assessment.

The applicant submitted the following statement after the meeting:

"*The applicants submitted to the secretariat, in due time before BPC-37 (19-11-2020, ARN-C-1482287-03-00/F), a letter for distribution among the MS's with clarifications on how to scientifically use experimental T25 data for human risk assessment. This document was prepared after changes were made to the T25 calculations at the BPC-36 follow up WG meeting (19-10-2020). The derivation of T25 is essential to the outcome of the risk assessment and the applicants request that the derivation of T25 is revisited. Further discussion on T25 at BPC-37 was cut short, with a claim that all scientific discussions had been closed at BPC-36. As it stands the applicants disagree with the draft opinion in total, as all evaluations are based on unrealistic assumptions in part introduced after BPC-36*."

The section brush application was revised as agreed at BPC-36 and new calculations for worker exposure were presented by the rapporteur. Concerns were expressed by the BPC members since high risks could be posed to workers and the environment, especially if the brushing application is taking place outside of industrial settings (e.g. in the field at installation sites of poles) without proper risk management measures. It was pointed out that the conditions of use for the brushing application should be clearly described in the RAR and it should be highlighted that this use is considered an exceptional application method. It was also pointed out that there is no efficacy data provided in the RAR for the brushing application.

The applicant had submitted several comments on the RAR. However, technical issues were not reopened for discussion by the BPC. Some comments and editorial changes were agreed and will be incorporated when finalising the RAR.

Opinion

After BPC-36, a second draft of the opinion was prepared and shared for commenting for BPC-37. The second draft was further amended based on the discussions at BPC-37. The main points of discussion are summarised below (ad 1-4):

1) *Assessed uses and overall conclusions of the human health and environmental risk assessment*: In the summary of assessed uses, the Commission asked to include a further layer of detail regarding the uses that were evaluated and the uses that were not covered in the assessment as this was not clear from the proposed draft opinion, and remarked that some uses presented as assessed seemed to have been partly assessed due to lack of data. This was not considered necessary by the BPC members, taking also into account that a comprehensive description is provided in the RAR. It was also again underlined that the brushing application should be regarded only as an exceptional use and should be avoided as far as possible (e.g. cutting of the wood article after pressure impregnation should be avoided). From the uses incorporated in the renewal application, the hot and cold impregnation was not evaluated due to a lack of data.

Regarding human health exposure, it was requested to provide further description of the PPEs considered in the exposure assessment and their impact on the outcome of the risk assessment (ie. whether they reduce the risks to tolerable levels or not). It was explained that the exposure assessment is based on monitoring data for electricity pole installers only, with a poor description of the PPE applied in the study. Only in the risk assessment of the brushing application a modelling approach was applied. Due to this, it was not possible to assess if the suggested RMMs would lead to an amendment of the risk assessment conclusion from “non-tolerable” to “tolerable”. To minimise the risk as much as possible, a maximum list of RMMs was included. It was pointed out that despite of the risk assessment methods used, it is clear that maximal PPE should be in place in all uses since creosote meets the exclusion criteria.

Regarding the environmental assessment, it was clarified that in the railway sleepers’ scenario in use class (UC) 3, groundwater is the main receiving environmental compartment and emissions to soil are not considered to be relevant (Emission Scenario Document for PT8). The sleepers are not in direct contact with soil and the structures right below the railway sleepers is considered to belong to the technosphere.

The terminology of the risk characterisation and the overall conclusions were discussed. As per BPR Article 19(1)b (and BPR Annex VI point 48 in particular for PBT substances), as an outcome of the evaluation it should be concluded if the biocidal product has an unacceptable effect on the environment. This is not straightforward in case of creosote as

the current methodology for quantitative risk assessment is considered insufficient for substances meeting the PBT/vPvB criteria: a residual risk remains even if the predicted environmental concentration (PEC) for a certain use is estimated to be below the predicted no-effect concentration (PNEC). Therefore, even if the quantitative assessment indicates PEC/PNEC < 1, RMM would still be needed to reduce the emission to the environment. It will be stated in the opinion for creosote that it was not demonstrated that there are no unacceptable effects to the environment.

As a general item concerning substances meeting the PBT/vPvB criteria, the ENV WG will be asked to provide a wording for the risk assessment outcome that is in line with the BPR Annex VI (point 48) and BPR Art 19(1). However, from the scientific assessment point of view, there is no change in the assessment. The Commission asked that the implementation of point 48 of Annex VI is addressed in the opinion.

Overall, in the case of creosote, it was considered that the terminology used will not be critical in terms of the overall outcome of the evaluation. When the predicted risks to human health and the environment are taken together, there is no safe use identified for any of the scenarios assessed. Furthermore, it was acknowledged that a data gap exists regarding the ED assessment, while normally a conclusion is need for all substances. Since creosote already meets the exclusion criteria (non-threshold carcinogen) there would be however no change in the risk management measures needed to be applied, while there is an urgency to finalise the renewal process. It was also noted that COM is still further investigating whether the requirement for an ED assessment can be adapted for substances already meeting other exclusion criteria. COM noted that it will take due account of this data gap for creosote, and consider how to address it in its decision-making process.

Finally, the applicant expressed their disagreement to the overall conclusion of the evaluation and submitted the following statement after the meeting to be included in the minutes: "*We, the applicants disagree with the draft opinion in total as all evaluations are based on unrealistic assumptions in part introduced after BPC 36. Comments of the applicants with a focus on corr. T25 were neglected claiming that the technical discussion had been closed at BPC-36*."

2) *Analysis of alternatives*: Substantial information was provided in the public consultation on candidates for substitution and an extensive analysis of the received information was provided in the RAR. When discussing the overall conclusions presented in the draft opinion, there was agreement that alternatives are available for the uses of creosote. However, regarding the progress of the implementation of alternatives, the situation in Member States (MS) differ across the EU. In one MS as a result of long experience and implementation, creosote products and treated articles are not used at all and alternatives are in place for all uses. Other countries on the contrary may be early in the process of substituting creosote and additional time is needed to enable the necessary progress on the implementation in practice in those Member States. For instance, some MS may have specific uses for which it is more difficult to find alternatives due to the geographic characteristics of their territory. In this case it may not be possible to substitute creosote for such an essential use. In this regard, COM would welcome further information to better understand for which uses substitution will be more difficult and in which Member States these difficulties are present. It was in addition pointed out by several members that further guidance is needed for the analysis of alternatives under biocide assessment.

COM remarked that this section in BPC opinions still needs to be improved. On the present case, COM considered that the BPC should have reflected further information coming from the biocidal product authorisation stage in the draft opinion. It further stressed that it is important that Member States analyse the situation on their own territory and provide further information on the matter in the next steps of the discussion on the renewal of creosote.

3) *Conditions of the renewal of the approval (Section 2.3 of BPC Opinion)*: As a proposal, a condition for biocidal products was included to indicate that products shall not be used to treat wood that can be expected to be in contact with, above or in vicinity of surface water, since some components of creosote are identified as priority substances under the Water Framework Directive (WFD). However, a number of BPC members did not support this condition. Certain countries for instance have essential uses of creosote treated wood close to surface waters with no suitable alternatives available. Although research is on-going, more time is needed to apply these potential alternatives in practice in those Member States. Based on these considerations, the proposed condition will not be included. However, a reference to the relevant provisions in the WFD will be highlighted elsewhere in the opinion.

The conditions and restrictions for storage of creosote treated articles outside treatment plants were discussed. Importantly, the conditions for temporary and longer-term storage were distinguished. It was pointed out that for temporary storages with limited time-periods certain arrangements may be impractical. However, for outdoor storage over long period of time prevention of environmental emission is crucial. In addition, access of the general public should be prevented at temporary storage sites. The storage related conditions will be further considered by COM as these may be partly overlapping with the restriction under REACH. COM was also interested to receive information from the members from previous national authorisations e.g. regarding labelling conditions.

An intensive discussion took place regarding a proposal to introduce restrictions on the trade of creosote treated wood between MS. In short, according to the proposal, MS should authorise products only to be used to treat wood for purposes that have been authorised in the receiving MS. Several members expressed their concern over this proposal and it was considered that more discussion and reflection is required before such a condition can be included. Questions were raised for instance regarding the practical implementation and enforcement or how this issue can be handled in countries where no products are authorised. The proposal will need further discussion. COM indicated the issue will be taken into consideration in the further process once the opinion is adopted. As another item related to treated articles, a labelling condition related to marketing of second-hand creosote treated articles to the general public was included for COM consideration, referring to the restriction under REACH (REACH Annex XVII entry 31.2.c).

4) *Elements to consider at product authorisation and requirements for further information*: At the previous BPC-36 discussion, the applicant and the rapporteur were asked to provide information on the composition (5-batch analysis) and the residue definition. The rapporteur explained that 5-batch analysis information on the composition was not provided by the applicant, since time-wise this was not feasible before the BPC-37. It was reiterated that this information was not requested to the applicant during the evaluation phase. Since the first approval of creosote was under the BPD, the EN norm was followed and the provided Certificates of Analysis (CoA) comply to that. It was also noted that the requirement of 5-batch analysis for renewal evaluation was introduced in the Renewal Guidance finalised in May 2020.

It was accepted by the BPC members that the 5 batch-analysis will be required before the next renewal of creosote. For creosote being a complex UVCB substance, considerable time will be needed to develop and validate the analytical method as well as perform the analysis. The same analytical methods will be used for monitoring purposes. The applicant requested further information from the authorities to be able to define which components should be analysed and monitored. It was pointed out by a BPC member that at product authorisation stage a clear list of the agreed marker substances has to be available and it has to be clear in the submitted data from the applicant that the monitored constituents are part of the active substance/biocidal product.

As was concluded by the Human Health WG, and reconfirmed by the BPC, it is stated in the opinion that any uses leading to residues in food are considered unacceptable, for instance for the use of treated tree support posts and equestrian/agricultural fencing. A requirement for product authorisation was therefore proposed to demonstrate the absence of residues. On the other hand, the monitoring study available from the applicant already indicated residues in food (fruits) for the use of creosote in tree support posts. It was also noted that, at least in certain countries, there is a lack of suitable alternatives for these type of uses. Therefore, monitoring data on the selected constituents (according to the residue definition) has to be provided when authorising products if a use leading to potential food residues is in place. In this regard, for the use in tree support poles (and other uses in agricultural and equestrian fencing potentially leading to food residues), no conditions or restrictions were included. COM expressed concerns that there are still issues with the residue definition and the absence of validated analytical methods although products have been authorisation and being already at the renewal process. It called the applicant, the eCA and ECHA to addresss the matter.

One member pointed out that in the human health assessment, no RMMs were identified to prevent and/or minimise the secondary exposure of general public. This would lead to issues at the product authorisation stage, since in the opinion it is stated that products for impregnation of poles/equestrian fencing should not be authorised if the risk cannot be reduced to a tolerable level by risk mitigation. If the use for tree support poles will be approved at active substance level and there are no RMMs indicated, it is not clear how it will be possible to authorise the related creosote products. This issue is open for discussion in the forthcoming steps in the renewal process of creosote.

The opinion was adopted by majority with a proposal for renewal. One member will submit a minority opinion regarding import and trade of treated articles.

Follow-up / Other issues

It is expected that the post-renewal data requirements will need to be discussed in detail by the authorities and the applicant. Further discussion is also expected related to the articulation with REACH, where COM will further consider whether some proposals for the making available on the market of treated wood fit better under REACH.

PL informed that a discussion for the dossier on harmonised classification and labelling has been started but for the moment the timelines for the submission cannot be indicated.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 15 January 2021.

- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM by 18 December 2020 and publish it on the ECHA website.

7.3 Draft BPC opinion on diamine for PT 8

The Chair welcomed the applicant. The stakeholders were allowed to be present during the discussion.

The rapporteur briefly introduced the case and indicated that diamine PT 8 is a backlog dossier with a long discussion history. It has been discussed at several Technical Meetings where all the sections were closed except for human health assessment. A revised evaluation was submitted to ECHA in 2016, which was been discussed at Working Group meetings in 2016 and 2020. The long duration of the evaluation and peer-review together with the proposal for non-approval triggered intensive discussions on certain points of the human health risk assessment including possible risk mitigation measures. These points are summarised below.

The number of cycles per day for the vacuum pressure treatment used in the exposure assessment for the industrial user was discussed. Lowering the number of 3 cycles/day would lead to acceptable risks and therefore provide a safe use. This was already discussed at the Working Group – Human Health meeting (including an ad-hoc follow up discussion) where it was decided to stick to the default value of 3 cycles/day as this reflects a realistic worst-case conditions under which the biocidal product may be used and considering that it may not be possible to enforce. The applicant claimed that the reduction to less than 3 cycles/day as a legitimately possible scenario and reminded that it was previously considered by the rapporteur in their assessment. The applicant also stated that it would be feasible to implement such a measure as a label condition considering it as a realistic and enforceable scenario in treatment plants. A couple of members supported the reduction to less cycles/day. One member informed of a national authorisation product (and a mutual recognition) where such a measure was accepted for authorising a biocidal product. The Chair clarified that the realistic worse case is 3 cycles as laid down in the guidance documents for estimating exposure for wood preservatives. Some members stated that it was difficult to form an opinion on this aspect as this was already discussed and concluded in the Working Group. It was explained that since not all MSCAs are represented in the Working Group – Human Health it is possible to reopen issues and discuss at BPC. The BPC members finally agreed on not lowering the number of cycles as a risk mitigation measure and stick to the default value from the guidance.

Further refinements in the vacuum pressure treatment were then discussed. The applicant proposed a couple of recalculations: a) the reduction of the in-use concentration from 0.025 % to 0.02 %; or b) the reduction of the dermal absorption from 2.5% to 2%. Using these according to the applicant slight modifications would not lead to unacceptable risks, even when using the default values of 3 cycles/day. The rapporteur could support the a) reduction of the in-use concentration only if the efficacy is demonstrated at this lower in-use concentration, but could not support a reduction of the dermal absorption value.. ECHA checked and confirmed during the meeting that the efficacy seems to be demonstrated at this lower in-use concentration and that the calculations provided by the applicant indicate that the percentage of the exposure is below the long-term AEL being 99%. Some members indicated their concerns with changing the assessment at the BPC claiming that

this is too late in the process. The applicant claimed that all the information was available in the dossier and reasoned that bringing the discussion to the BPC, also because only at a very late stage the applicant was informed that a non-approval will be proposed by the rapporteur. The discussion focussed mainly on the acceptability of these changes at the BPC without further consultation possible. A member indicated that the calculations are straightforward therefore could accept them. Nonetheless, the majority of the BPC members considered that, although efficacy could probably be demonstrated, the assessment should not be reopened by the BPC members.

Another aspect raised by the applicant related to dermal absorption. The applicant considered that the value of 2.5% used in the evaluation was too conservative and stated that further data is under development which clearly demonstrates - based on preliminary results - that the value is considerably lower. These data could be provided at product authorisation. The rapporteur did not agree to amend the dermal absorption at this stage and stated that no new information can be considered. The BPC members agreed with the rapporteur that no new information can be considered at this stage.

Regarding the secondary exposure one of the scenarios leads to an unacceptable risks. The applicant complaint that not enough efforts were made to reach an acceptable exposure, which the applicant claimed to be possible with further refinements to the Tier 1 assessment performed (such as reconsidering the double counting of the oral and dermal exposure). The Commission inquired if the risk could be mitigated by possible risk management measures. It was clarified by the Chair that this was not discussed by the Working Group – Human Health as it was not considered necessary by the rapporteur to discuss the possibility of further refinements of the scenario. The BPC decided not to amend the evaluation but that it would be indicated in the opinion that it may be further refined.

All the other issues indicated in the open issues table were discussed and agreed. The assessment report was agreed, and the BPC opinion was adopted via a voting procedure by majority. Eight members abstained and two provided a minority position.

The applicant stated its disagreement with the process reminding that the draft assessment was already submitted by the rapporteur for peer review a long time ago under Biocidal Products Directive (BPD) 98/8/EC where it contained an approval proposal until just before the BPC meeting. COM also regretted that the peer review on this active substance took so long, these situations should be avoided. COM further stressed that Member States having backlog reports submitted under Directive 98/8/EC should contact ECHA and make progress in the peer review.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 15 January 2021.
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **Member (CZ, SK)**: to submit the minority position by 9 December 2020.
- **SECR:** to forward the adopted opinions to COM by 18 December 2020 and publish it on the ECHA website.

7.4 Article 75(1)(g)

7.4.1. Draft BPC opinion on the availability and suitability of alternatives to boric acid and disodium tetraborate pentahydrate for PT 8

The Chair welcomed the applicant. The stakeholders were allowed to be present during the discussion. The rapporteur introduced the opinion and the process followed, where CTGB, RIVM and SKH (Dutch Certification Body for Wood and Wood Preservatives) were involved. It was pointed out by the rapporteur that the time schedule was tight and that there is a lack of guidance for the analysis of alternatives.

Given the novelty of the procedure and, pointing towards learning from this experience and how to improve the process, in addition to the discussion on the items collected in the open issue table, the Chair invited the BPC members to provide general comments on the opinion. Those comments and the discussions triggered are described below, together with those from the open issue table.

The BPC members and the Commission expressed their appreciation to the work done, despite the challenges confronted as previously mentioned. The Commission clarified that the request came from the Standing Committee and acknowledged the difficulty of a more thorough analysis given the circumstances already mentioned and pointed to the substantial improvement on the information collected on alternatives compared with previous opinions.

The Commission welcomed the request for guidance expressed by the rapporteur and BPC members, and indicated that in fact most of the experience must come from the MSCAs as they perform the comparative assessment at product authorisation. The Chair indicated that ECHA is committed to work on further improving the process in the coming year and stated that the experience from the authorisation process under REACH where the analysis of alternatives is also performed, may be a source to learn from.

The selection criteria for the substances to consider as alternatives was discussed. The rapporteur explained that candidates for substitution and substances (CfS) meeting the exclusion criteria were not considered and that a couple of CfS were not considered given that there are none or a very limited number of product authorisations. It was noted that the search of alternatives in biocides is an area where the MSCAs are still building their expertise, and since the aim is to find substances that are essentially better, some members, supported by ECHA and the Commission, preferred not to exclude any CfS a priori: a tiered approach was suggested. The Commission disagreed excluding alternatives with a limited number of authorisations as this situation may change over time due to the dynamics of the markets, and that banning an active substances bring also more space for alternatives.

Regarding the negative impact from the applicant perspective mentioned by the rapporteur, the Commission acknowledged their understanding on the applicants desire to have the same level of protection, but questioned whether it would not be possible to have a somewhat more costly but safer alternative. The Commission also questioned if the unique properties mentioned in the mode of action will really be lost when changing to an alternative or could this function be performed by a combination of several other substances, e.g. for the fire protection. The rapporteur explained that the time constriction did not allow the assessment of such practicalities.

The rapporteur indicated the importance of knowing the technical properties in the decision on the suitability of an alternatives; mainly to determine the feasibility of the alternatives. It was noted that some alternatives might not be applicable for certain products, where additional treatments might be needed, for example the replacement of borates by IPBC in class 3 as an anti-sapstain would require an additional coating. The rapporteur also expressed their concerns that for most products the information is available only in local language, and not in English and that the data are also not reported consistently. ECHA clarified that the more recent authorisations contain the SPC where the information is also displayed in English; and that the SPC tool will facilitate the task for future analysis.

Another point for discussion was the socio-economic impact including the costs of alternatives compared to borates. It was mentioned that there are judgements regarding the higher cost for alternatives in the draft opinion, where the rapporteur stated that they lack knowledge for this kind of analysis. The rapporteur explained the different actual price/use, which depends on the use (class 1-4) and application rates. The difficulty how to weigh the economic impact compared to other criteria was acknowledged where it was suggested to include in the opinion explanations on how the analysis was done. In addition, it was mentioned that the costs of alternatives are part of the analysis but that the socio-economic impact belongs to the evaluation on whether Article 5(2) is met or not.

The question on whether the renewal should be limited or restricted to uses where no sufficient and suitable alternatives are available was raised. The rapporteur considered that this would require further analysis; for this opinion they focussed on for which uses there are no suitable alternatives available which was within the scope of the mandate to ECHA. It was decided to amend the conclusions in this respect.

The opinion was adopted by consensus. It was concluded that the exercise will also be useful for other substances in the same situation; the need for further guidance was noted and the next steps were outlined: once the final opinion will be received by the Commission, it will be discussed at the Standing Committee in relation to Article 5(2).

Actions:

- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM by 18 December 2020 and publish it on the ECHA website.

7.5. Draft BPC opinion on ethylene oxide for PT 2

The Chair welcomed the applicant. The stakeholders were allowed to be present during the discussion. Only 3 comments were left open on the Assessment Report. The Chairman commented that the Assessment Report will be amended where required and considered by the rapporteur following several more editorial comments by the applicant. The other comments were agreed by the rapporteur and the assessment report will be amended accordingly. The BPC agreed on the assessment report.

Then the discussion focussed on the comments received for the draft BPC opinion, as included in the open issues table.

The Chair proposed to discuss first the comments relating to the human health section and more specifically a statement in the draft opinion concerning the OEL value which is in place in the workers legislation (Directive (EU) 2017/2398) and the DMEL value which has

been derived for professionals. The Chair referred to the significant difference between the OEL and the DMEL value. It was agreed to bring the difference to the attention of the Commission in the letter by which ECHA transmits the adopted opinion.

Another comment was related to the ED assessment in the section on exclusion and substitution criteria. In the draft opinion, there is a statement that according to the existing guidance further testing would in principle be required to conclude on the ED properties. However, for ethylene oxide, there is no added value and it is argued that no further data should be requested. The Chair recommended that instead of referring to the added value of additional testing, to refer to Annex IV of the BPR. The Commission stated that from a regulatory perspective the waiving according to Annex IV would maybe not be enough for the decision making. The Commission highlighted that it is also very important to make clear from a technical perspective why additional data is not being requested (on the one side that the substance is very reactive while on the other side, it will be very difficult, if not impossible to differentiate an ED mode of action from other effects brought by the substance).

A discussion took place about the analysis of alternatives as a result of the public consultation. A member asked if more detailed information is available to quantify the costs and the time scale of substitution to reach a conclusion on suitable alternatives. Furthermore, this member commented that it is important to them to know whether the burden of the costs will be on the producer or on the society. The rapporteur explained that there is some information on costs but no precise quantification. The rapporteur and applicant provided some more information on the on-going work on alternatives including on the time horizon for the availability of these alternatives. It was decided to add this information to the opinion.

The Committee thoroughly discussed a provision for product authorisation regarding the conditions about the monitoring data in air as a result of the identified unacceptable risks for the general public in the surrounding areas of industrial sterilisation plants. A member commented that the monitoring data in air should be provided at product authorisation stage to assess the risk for the general public and the environment. Another member and the Commission questioned for which purpose the monitoring data will be used: (i) to refine the risk assessment and/or (ii) to confirm the model calculations used in the assessment. During the discussion, the need for the operator of the plant to monitor the concentrations in air in the vicinity during use was considered necessary to demonstrate that the DMEL is not exceeded. The members agreed to include in section 2.3 of the opinion two separate conditions concerning these different purposes of the monitoring data.

The Commission expressed concerns that a fully validated analytical method for the detection of ethylene oxide in air is still lacking as this active substance has been under examination for a long time in the review programme.

All the remaining issues indicated in the open issues table were discussed and agreed by the Committee. All conclusions are recorded in the open issue table. The assessment report was agreed and the BPC opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 15 January 2021.
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.

- **SECR:** to forward the adopted opinions to COM by 18 December 2020 and publish it on the ECHA website.

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

7.6.1. Cyphenothrin for PT 18

The involved evaluating CA Greece informed the meeting that they accepted the post approval data submitted by the applicant and responded to the comments received in the Newsgroup by the BPC members. The evaluation performed was agreed by the meeting.

Actions:

- **Member (EL):** to forward the revised assessment report with the List of Endpoints to the SECR by **15 January 2021**.

7.6.2. 1R-trans phenothrin

The involved evaluating CA Ireland informed the meeting that they accepted the post approval data submitted by the applicant. The evaluation performed – which was discussed at the Working Group Environment - was agreed by the meeting.

Actions:

- **Member (IE):** to forward the revised assessment report with the List of Endpoints to the SECR by **15 January 2021**.

7.7. CMK: request an analytical method for the detection of aerosols at active substance renewal stage or at product authorisation level?

The document was introduced by the SECR and the member from DE. After some discussion it was concluded by the Chair that the meeting agreed to the proposal of DE to request such data first at the active substance renewal stage. In addition it was concluded – following a remark from one of the members – to have a generic discussion on this issue at the APCP Working Group. The SECR was asked by the BPC to organise this discussion.

8. Union authorisation

8.1 Update on Union authorisation

An update on Union authorisation was given by the SECR: i) an overview of the current status of the UA-APP and UA-BBP applications in ECHA's pipeline; ii) procedural issues

Ad i) The usual table with ongoing Union authorisations was shown. In general there is little progress for the cases, which is a concern. The Commission echoed the concerns of SECR on the matter and on the need to meet the 3-year deadline for deciding on Union authorisations.

Actions:

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

8.2 Harmonized approach to determine a worst case (or representative) test product for a disinfectant biocidal product family

A document discussed at the EFF WG clarifying how the bridging studies should be designed to substantiate the choice of the worst-case test product to be used for the core efficacy assessment for disinfectant BPFs (PT 1-5) was presented to the BPC.

The BPC agreed with the proposal without further discussion.

Actions:

- **SECR** to inform the BPC and CG members when the document is published on the ECHA EFF webpage.

8.3 Draft BPC opinion on an Union authorisation application for a biocidal product family containing CMIT/MIT

The Chair welcomed the applicant. The stakeholders were allowed to be present during the discussion. The rapporteur introduced briefly the dossier related to a biocidal product family C(M)IT/MIT aqueous 1.5 – 15 containing C(M)IT/MIT (3:1). The family is composed of 4 meta-SPCs with 28 different uses. The following open points were discussed during the meeting.

A discussion took place regarding a regulatory question on whether it would be possible to include risk mitigation measures for treated articles and so-called treated-treated articles in the SPC. This question was already raised in Coordination Group within several referrals that were referred to the Commission in accordance with Article 36. The Commission confirmed that internal consultations and discussion at CA level are still on-going. Therefore, as this issue has not been clarified yet, it was decided to adopt the opinion including the measures proposed by the rapporteur noting that the further discussion at CA level may impact the decision on the authorisation and its conditions.

A point was raised regarding the uses #1and #2 where 2 different treatments (oxidizer + CMIT/MIT) are happening subsequently in a short time slot of few minutes. The Commission reminded that when biocidal products are used together there are some specific obligations in the annexes of the BPR that should be considered. The rapporteur clarified that oxidiser is not formulated neither mixed with CMIT/MIT based products, but there are two different distinct treatments with different objectives, and that the purpose of this tandem treatment is to optimise the biocidal treatment in general by reducing the quantity of oxidizer that must be introduced into the system. In addition, it reduces the contact time to achieve faster the expected efficacy. A member requested that the question on whether the application of the oxidizer needs to be assessed in the risk assessment for the environment – including the possible formation of disinfection by-products - should be clarified from a regulatory perspective. The rapporteur clarified that an authorisation is required for the biocidal product containing the oxidiser and the risk assessment for the environment will be done for that biocidal product. Different opinions were expressed by the members however no clear majority appeared. Therefore, it was agreed to keep the rapporteur proposal.

Two comments were related to the corrosivity for the products in meta SPC-3. The eCA explained that although one study is not fully compliant there is enough data to make an expert judgement in order to conclude that the classification of the products should be “corrosive to metals”. A member argued that a new storage stability study with a longer duration would be needed to conclude, which can be requested as post authorisation data. The SECR considered the data not enough to conclude on corrosivity, and proposed not to classify the products. In the absence of a common agreement on the way forward, it was decided to keep the classification as “corrosive to metals” and not to request any post authorisation data.

A member expressed concerns about a sentence in the Product Assessment Report (PAR) related to the resistance reporting and asked whether it can be deleted. The member considered that the authority to contact for reporting would be ECHA in case of Union authorisation. The rapporteur agreed that it could be deleted but stated that progress would need to be made on resistance reporting for Union authorisation as for national authorisation Member States have a reporting system in place. The Commission reminded that resistance management is a horizontal policy issue that needs to be further analysed, and, therefore, will look into this further together with ECHA.

Regarding risk mitigation measures in the SPC, a member questioned the applicability of the measures proposed by the rapporteur for treated articles normally limited to professional users only but which may be distributed to the general public. To prevent this a measure was proposed by the member. The rapporteur clarified that the treated articles are not intended to be used by the general public and explained that use by the general public would be considered as misuse. Therefore, there is no reason to add a measure noting this will also create a precedent to be considered also for national authorisation. The Chair invited the members to provide feedback on their national practice in such a situation. Different views were expressed by the members. The Commission pointed out that the risk mitigation measures should be applied to minimise the risk from the proposed use of the product. It was agreed not to amend the SPC.

All further items in the open issues table were addressed. The BPC opinion, the draft SPC and the PAR will be revised according to the conclusions taken at the BPC and as reflected in the open issue table. The BPC opinion was adopted by majority.

Actions:

- **Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by 15 January 2021.
- **Member (DE):** to submit the minority position by 10 December 2020.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by 18 December 2020.

9. Any Other Business

9.1 Confidentiality check in working procedures for active substance approval

This agenda item was not discussed and it was postponed to the next BPC meeting.

9.2 EBPF becomes Biocides For Europe

This agenda item was not discussed and BPC members were informed about the change by email.

10. Agreement of the action points and conclusions

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

Part II - Main conclusions and action points

Main conclusions and action points

Agreed at the 37th meeting of BPC

1-4 December 2020

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom / by when)**
Item 2 - Agreement of the agenda	
The final draft agenda was agreed without changes.	**SECR:** to upload the agreed final agenda to the BPC CIRCABC IG as part of the draft meeting minutes after the meeting.
Item 4 - Agreement of the minutes and review of actions from BPC-36	
The revised version of the minutes of BPC-36 was agreed.	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website.
Item 5 – Administrative issues	
-	-
Item 6 - Work programme for BPC	
6.1 BPC Work Programmes for active substance approval, Union authorisation, ED assessment and outlook for BPC	
-	**Members:** to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by **11 December 2020.**
Item 7 - Applications for approval of active substances	
7.1 Procedural and administrative aspects:	
7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval	
The BPC took note of the document.	-

7.2 Draft BPC opinion on the renewal of creosote for PT 8	
The BPC adopted by majority the opinion on the application for the renewal of the approval of the active substance PT combination.	**Rapporteur**: to revise the renewal assessment report in accordance with the discussions in the BPC and submit to the SECR by **15 January 2021.** **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 (SE):** to submit the minority position by **11 December 2020**. **SECR:** to forward the adopted opinion to COM by **18 December 2020** and publish it on the ECHA website.
7.3 Draft BPC opinion on diamine for PT 8	
The BPC adopted by majority the opinion on the non-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 **15 January 2021.** **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 (CZ, SK):** to submit the minority position by **9 December 2020**. **SECR:** to forward the adopted opinion to COM by **18 December 2020** and publish it on the ECHA website.
7.4 Article 75(1)(g)	
7.4.1. Draft BPC opinion on the availability and suitability of alternatives to boric acid and disodium tetraborate pentahydrate for PT 8	
The BPC adopted by consensus the opinion.	**Rapporteur:** to revise the draft opinion in accordance with the discussions in the BPC and submit to the SECR by **14 December 2020**. **SECR:** to forward the adopted opinion to COM by **18 December 2020** and publish it on the ECHA website.
7.5 Draft BPC opinion on ethylene oxide for PT 2	
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 **15 January 2021.** **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 **18 December 2020** and publish it on the ECHA website.

	SECR: to inform COM when submitting the opinion on the discrepancy between the OEL and the DMEL for professionals.
7.6 Revised Assessment Report following the submission of data after active substance approval:	
7.6.1. Cyphenothrin for PT 18	
The member from EL informed the BPC about the evaluation of the data submitted after the approval. The evaluation was agreed upon.	**Member (EL):** to forward the revised assessment report with the List of Endpoints to the SECR by **15 January 2021. [**SECR to check first if this is needed.**]**
7.6.2. 1R-trans phenothrin	
The member from IE informed the BPC about the evaluation of the data submitted after the approval. The evaluation was agreed upon.	**Member (IE):** to forward the revised assessment report with the List of Endpoints to the SECR by **15 January 2021. [**SECR to check first if this is needed.**]**
7.7. CMK: request an analytical method for the detection of aerosols at active substance renewal stage or at product authorisation level?	
The BPC agreed on the proposal from DE as indicated in the document to request the method at renewal stage of the active substance approval for CMK.	**SECR:** i) to inform the Coordination Group; ii) initiate a discussion at the APCP WG on the need for analytical methods in vapours and/or aerosols at active substance approval stage in case of a spray application as the representative product.
Item 8 – Union authorisation	
8.1 Update on Union authorisation	
The BPC took note of the presentation provided by the SECR.	**SECR:** to upload the presentation on the BPC CIRCABC IG.
8.2 Harmonized approach to determine a worst case (or representative) test product for a disinfectant biocidal product family	
The BPC discussed and agreed the document.	**SECR**: to publish the document on the BPC CIRCABC IG and the ECHA website and inform the Coordination Group.
8.3 Draft BPC opinion on an Union authorisation application for a biocidal product family containing CMIT/MIT	
The BPC adopted by majority the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **15 December 2021.** **Member (DE):** to submit the minority position by **10 December 2020**. **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.

	SECR: to forward the adopted opinion, draft SPC and final PAR to COM by **18 December 2020** and publish them on the ECHA website. **SECR:** to inform COM when submitting the opinion concerning the issue about risk mitigation measures for treated (treated) articles.
Item 9 –Any other business	
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Part III - List of Attendees

Members	COLLET Romy (FR)
BORGES Teresa (PT)	CONROY Kenneth (IE)
CARBERRY Stephen (IE)	COUGNON Thomas (BE)
CEBASEK Petra (SI)	EHNI Markus (DE)
CHEZEAU Aurelie (FR)	FRANK Ulrike (SE)
DRAGOIU Simona (RO)	FRYDENLUND Jorid (NO)
GONZALEZ MARQUEZ Maria Luisa (ES)	GARRÃO Maria (PT)
GREGERSEN Nina Falk (DK)	GATOS Panagiotis (EL)
HAHLBECK Edda (SE)	GKILPATHI Dimitra (EL)
HAKAITE Palmira (LT)	GÓRECKI Roman (PL)
JAGER Stefanie (DE)	GOUR Annabelle (FR)
JOHN Nina (AT)	HAMALAINEN Anna-Maija (FI)
KOIVISTO Sanna (FI)	HORCZYCZAK Anna (PL)
LANS Martine (NL)	IAKOVIDOU Mary (SE)
MERISTE Anu (EE)	KALKERS Lucas (NL)
MIKOLAS Jan (CZ)	NIEMINEN Timo (FI)
MIKOLASKOVA Denisa (SK)	OLIVEIRA Ana Barbara (PT)
RANDALL Marit (NO)	PENTTINEN Sari (FI)
SZENTGYORGYI Timea (HU)	RIFFAUT Lea (FR) *
VAGIAS Vasileios (EL)	RZODECZKO Helena (PL)
VRHOVAC FILIPOVIC Ivana (HR)	SCHOEP Piet (NL)
ZIGRAND Jeff (LU)	WEINHEIMER Viola (DE)
Alternate members	**European Commission**
JARRETY Helene (BE)	CAINZOS GARCIA Marta (DG SANTE)
KRAFTE Kristina (LV)	CHATELIN Ludovic (DG SANTE)
PUERGY Reinhild (AT)	DELVAUX Vincent (DG SANTE)
PYTHON Francois (CH)	GKINIS Georgios (DG SANTE)
TERNIFI Vesna (SI)	NAGTZAAM Martinus (DG SANTE)
Advisers	**Invited experts**
AAMODT Solveig (NO)	HUSZAL Sylwester (PL)
ALMEIDA Francisca (PT)	

Accredited Stakeholder Observers	Apologies
BARBU Luminita	CY
CINGOTTI Natcha	IT
DREVE Simina-Virginia	MT
SPANG Günter	
VAN BERLO Boris	
Applicants	
Creosote Council. Europe (CCE)	
Borax Europe Limited and Etimine s.a.	
ETO Biocides Consortium	
Lonza Cologne GmbH	
Nutrition & Biosciences Netherlands B.V.	
Sumitomo Chemical (UK) Plc	
ECHA Staff	
CARLON Claudio	
HONKA ANNI	
JARDIN Helene	
GLANS Lotta	
KURONEN Terhi	
LAITINEN Jaana	
PAPADAKI Paschalina	
SAEZ RIBAS Monica	
SZYMANKIEWICZ Katarzyna	
VAN DE PLASSCHE Erik	
VAN DER LINDEN Sander	
VAN GALEN Joost	

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-37

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-37 meeting

Meeting documents		
Agenda Point	**Number**	**Title**
2	BPC-A-37-2020_rev1	Draft agenda
4	BPC-M-36-2020	Draft minutes from BPC-36
5.1	-	Administrative issues and report from the other Committees
6.1	BPC-37-2020-01 BPC-37-2020-02 BPC-37-2020-03 BPC-37-2020-04	BPC Work Programme for active substance approval, Union authorisation, ED assessment and outlook for BPC
7.1	BPC-37-2020-05	7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval
7.6	BPC-37-2020-10	7.6.1. Cyphenothrin for PT 18
	BPC-37-2020-14	7.6.2. 1R-trans phenothrin
7.7	BPC-37-2020-11	CMK: request an analytical method for the detection of aerosols at active substance renewal stage or at product authorisation level?
7.6	BPC-36-2020-16	7.6.1. Active chlorine release from sodium hypochlorite for PT 1 - 5 7.6.2. Active chlorine release from calcium hypochlorite for PT 2 - 5 7.6.3. Active chlorine release from chlorine for PT 2 and 5
8.2	BPC-37-2020-12	Harmonized approach to determine a worst case (or representative) test product for a disinfectant biocidal product family
9.1	BPC-37-2020-15	AOB: SE proposal to revise Working procedures AS

Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.2	BPC-37-2020-06A	Renewal of creosote PT 8	Draft BPC opinion
	BPC-37-2020-06B		Renewal assessment report
	BPC-37-2020-06B1		Conf Annex to Renewal assessment report MS only
	BPC-37-2020-06C		Open issues
	BPC-37-2020-06D_Room doc 1		Brushing tier 1 and 2 calculations
7.3	BPC-37-2020-07A	Diamine PT 8	Draft BPC opinion
	BPC-37-2020-07B		Assessment report
	BPC-37-2020-07C		Open issues
7.4	BPC-37-2020-08A BPC-37-2020-08B	Art.75(1)(g) Boric acid and disodium tetraborate pentahydrate PT 8	Draft BPC opinion
7.5	BPC-37-2020-09A	Ethylene oxide PT 2	Draft BPC opinion
	BPC-37-2020-09B		Assessment report
	BPC-37-2020-09B1		Appendix to assessment report: Summary of the public consultation
	BPC-37-2020-09C		Open issues
	BPC-37-2020-09D		RMMs adopted by the US EPA
8.3	BPC-37-2020-13A	UA: product family containing CMIT/MIT	Draft BPC opinion
	BPC-37-2020-13B		SPC
	BPC-37-2020-13C		PAR
	BPC-37-2020-13C1		Conf Annex to PAR
	BPC-37-2020-13D		Open issues

20 November 2020
BPC-A-37-2020_rev1

Draft agenda

37th meeting of the Biocidal Products Committee (BPC)

1 – 4 December 2020

Meeting is held virtually via WebEx

Starts on 1 December at 10:30, ends on 4 December at 13:00

The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-37-2020

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-36

BPC-M-36-2020

For agreement

5. – Administrative issues

5.1. Administrative issues

For information

5.2. Feedback received by SECR via questionnaire on virtual meeting in October

For information

6. – Work programme for BPC

6.1. BPC Work Programmes for active substance approval, Union authorisation, ED assessment and outlook for BPC

BPC-37-2020-01; BPC-37-2020-02; BPC-37-2020-03; BPC-37-2020-04

For information

7. – Applications for approval of active substances*

7.1. Procedural and administrative aspects:

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

BPC-37-2020-05

For information

7.2. Draft BPC opinion on the renewal of creosote for PT 8

Previous discussion: WG–I-2020, BPC-36

BPC-37-2020-06A, B, C

For adoption

7.3. Draft BPC opinion on diamine for PT 8

Previous discussion: WG–I-2020

BPC-37-2020-07A, B, C

For adoption

7.4. Article 75(1)(g)

7.4.1. Draft BPC opinion on the availability and suitability of alternatives to boric acid and disodium tetraborate pentahydrate for PT 8

BPC-37-2020-08

For adoption

7.5. Draft BPC opinion on ethylene oxide for PT 2

Previous discussion(s): WG-III-2020

BPC-37-2020-09A, B, C

For adoption

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

7.6.1. Cyphenothrin for PT 18

BPC-37-2020-10

For agreement

7.6.2. 1R-trans phenothrin

BPC-37-2020-14

For agreement

7.7. CMK: request an analytical method for the detection of aerosols at active substance renewal stage or at product authorisation level?

BPC-37-2020-11

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

For agreement

8. – Union authorisation**

8.1 Update on Union authorisation

For information

8.2 Harmonized approach to determine a worst case (or representative) test product for a disinfectant biocidal product family

BPC-37-2020-12

For agreement

8.3 Draft BPC opinion on an Union authorisation application for a biocidal product family containing CMIT/MIT

Previous discussion: WG-III-2020

BPC-37-2020-13A, B, C, D

For adoption

9. - Any other business

10. - Action points and conclusions

** For the discussions of the draft BPC opinions at least the following documents will be distributed: a draft BPC opinion (denoted by A), a draft Summary of Product Characteristics (SPC) (denoted by B), a draft product assessment report (PAR) (denoted by C) and a document containing open issues to be discussed for the biocidal product or biocidal product familiy (denoted by D).

Provisional time schedule for the

37th meeting of the Biocidal Products Committee (BPC)

Virtual meeting via WebEx

1 December 2020: starts at 10:30; 4 December 2020 ends at 13:00

Please note that the time schedule indicated below is provisional and subject to possible change. The schedule is distributed to participants on a preliminary basis. If needed, follow-up discussions may take place on the following day for BPC opinions.

Tuesday 1 December: (starts at 10:30, ends at 18:00)

Items 1-5	Opening items and administrative issues
Item 6.1	BPC Work Programme for active substance approval, BPC Work Programme for Union authorisation, Outlook for BPC, Status ED assessment for active substances
Item 7.1	Procedural and administrative aspects:
	7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval
Item 7.2	Draft BPC opinion on the renewal of creosote for PT 8

Wednesday 2 December: (starts at 10:30, ends at 18:00)

Item 7.3	Draft BPC opinion on diamine for PT 8
Item 7.4.1	Draft BPC opinion on the availability and suitability of alternatives to boric acid and disodium tetraborate pentahydrate for PT 8
Item 7.6	Revised Assessment Report following the submission of data after active substance approval:
	7.6.1. Cyphenothrin for PT 18
	7.6.2. 1R-trans phenothrin
Item 7.7	CMK: request an analytical method for the detection of aerosols at active substance renewal stage or at product authorisation level?

Thursday 3 December: (starts at 10:30, ends at 18:00)

Item 7.5	Draft BPC opinion on ethylene oxide for PT 2
Item 8.1	Update on Union authorisation
Item 8.2	Harmonized approach to determine a worst case (or representative) test product for a disinfectant biocidal product family
Item 8.3	Draft BPC opinion on am Union authorisation application for a biocidal product family containing CMIT/MIT

Friday 4 December: (starts at 10:30, ends at 13:00)

Item 7.2	Cont'd: Draft BPC opinion on the renewal of creosote for PT 8
Item 9	AOB
Item 10	Action points and conclusions

End of meeting

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