1 December 2020

BPC-M-36-2020

Minutes of the 36th meeting of the Biocidal Products Committee (BPC)

6-8 October 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 36th BPC meeting which took place as a fully virtual meeting via Secure Webex.

Regarding the BPC membership, the Chair stated that BPC member from Belgium has resigned and Belgium is in process to nominate a new member.

The Chair then informed the BPC members of the participation of 25 members, including two alternate members and two members whose official nomination is pending. In addition, Poland was represented by an invited expert.

26 advisers and 4 representatives from an accredited stakeholder organisation (ASO) were present at the meeting. Four 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-36-2020_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-35

The revised draft minutes from BPC-35 (BPC-M-35-2020), incorporating the comments received, were agreed.

The Chair noted that all actions from BPC-35 have been carried out.

The Chair further informed the meeting on the following:

- Opinions adopted in BPC-35 on active chlorine released from hypochlorous acid will be revised and re-published, as the statement of the relevant impurity sodium chlorate content needs to be corrected[1].
- 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 but could not yet agree on a proposal from FR. There will be a written consultation followed by a discussion at the next CG.
- Regarding "Harmonised List of Endpoints for synthetic pyrethroids": a Newsgroup was opened after the last BPC asking for agreement by the members. Following the agreement the harmonised LoEP was distributed by the SECR. One comment remained which will be discussed under agenda item 7.3.
- Regarding "Sensitisers and quantitative risk assessment (QRA)": this document was opened for comments via a Newsgroup. Subsequently, this issue was discussed at the last CA meeting. At the CA meeting it was: i) concluded that developing guidance on a QRA is not possible currently; ii) the Commission asked for comments of Member States and will develop a document for a next CA meeting on the possibility of risk management measures – including PPE – for non-professional use of preserved detergents, paints etc.
- At the CA meeting it was decided that CMIT can be considered as a new active substance.
- Post approval data: as informed at the BPC-35 meeting it was decided by ECHA to continue with section 2.5 discussions. The SECR informed involved members after the last BPC meeting. The Chairman thanked those who reacted and 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-35 to the BPC S-CIRCABC IG and to the ECHA website after the meeting.
- **Member from IE**: inform SECR on Ampholyt 20 discussion at next BPC.

5. Administrative issues

5.1 Housekeeping issues

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

The Chair presented the summary of the feedback received on the virtual BPC-35 meeting in June.

[1] Post meeting note SECR: the statement in section 2.3 of the opinions is changed into: "Sodium chlorate (relevant impurity): as dry weight max 2.96% w/w". The amended opinions have been published on the ECHA web-site.

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 17 opinions are scheduled to be adopted this year of which 16 are for the Review Programme. Also 10 opinions have been adopted for the Review Programme being returned opinions via 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 the outlook for 2020 contains 2 Article 75(1)(g): request on related to active chlorine generated via electrolysis – adopted last meeting – and a request related to the renewal of two borates. Three other Article 75(1)(g) requests did arrive since last meeting, which are – including the one on borates - on the agenda of this meeting.
- Maybe some Article 38 opinions will still be requested this year by the Commission: a maximum of 11 may arrive.
- Reference was made to the status of ED assessment for information purposes. The Chair mentioned that ECHA is preparing an overview for all active substances. This overview will be included in the ECHA reporting on the Active Plan on Active Substance Approval to the December CA meeting. 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.

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.

The Chair asked the eCAs being rapporteur for active substances or Union authorisations scheduled for discussion at the December 2020 BPC meeting (BPC-37), to confirm this planning to the SECR by 16 October 2020.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by 16 October 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.

7.1.2. Working procedure for active substance approval

The SECR introduced the main changes in the new proposal for the working procedure for active sustance approval:

- Inclusion of BPC agreement from 2019 that if the eCA proposes the classification of the substance as Muta 2, the RAC opinion on CLH should be available at the time of submitting the draft CAR to ECHA.
- A footnote has been included in the section of the commenting phase to clarify the scope of the commenting by the applicant, considering that the applicant is given the opportunity to provide comments on the assessment before the submsison of the draft CAR to the Agency.
- A note has been included clarifying the possibility for the applicant to reopen for discussion closed points that were raised by themselves during the commenting period.
- A note has also been included that eCAs should keep the applicant updated on the progress of ad-hoc follow-up discussions.
- The email address of ECHA active substance functional mailbox has been updated throughout the document.

The changes in the document were agreed with a slight wording revision for the second bullet point above to clarify that the comments from the applicant should be addressed, but not necessarily meaning that the changes proposed by the applicant are incorporated into the assessment.

Actions:

- **SECR**: to publish the revised working procedure on the BPC S-CIRCABC IG and the ECHA website.

7.2. Article 75(1)(g) requests received:

7.2.1. Evaluation of the level of the risks for human health and for the environment of DBNPA used in biocidal products of product type 4

The Chair informed the meeting about this request which is related to the one under agenda item 7.2.2 as both relate to the evaluation of the level of risks for an active substance which meets the ED criteria.

The BPC agreed with the proposal that the member from Denmark will act as the rapporteur for this request.

Actions:

- **SECR:** to coordinate this request with the one under agenda item 7.2.2.

7.2.2. Evaluation of the level of the risks for human health and for the environment of cyanamide used in biocidal products of product types 3 and 18

The Chair informed the meeting about this request which is related to the one under agenda item 7.2.1 as both relate to the evaluation of the level of risks for an active substance which meets the ED criteria.

The BPC agreed with the proposal that the member from Germany will act as the rapporteur for this request.

Actions:

- **SECR:** to coordinate this request with the one under agenda item 7.2.1.

7.2.3. Evaluation of the availability and suitability of alternatives to boric acid and disodium tetraborate pentahydrate for PT8

The Chair informed the meeting about this request. The BPC agreed with the proposal that the member from the Netherlands will act as the rapporteur for this request. The Chair reminded the BPC members to actively contribute to the on-going public consultation organised by ECHA on the availability of alternatives.

7.3. List of Endpoints for environmental exposure assessment for peracetic acid (PAA) and hydrogen peroxide

The document prepared by the SECR was discussed. Some views were expressed at the meeting. One MS expressed serious concerns in relation to ECHA's interpretation of Article 59 of the BPR and the use of data from one company for the benefit of a third party. This MS also gave attention to a question sent to ECHA in July 2019 on procedural and legal aspects which are strongly related to this issue (e.g. use of active substance data submitted during product authorisation; what triggers a need to revised the List of Endpoints?). These issues are still under consultation between ECHA and COM and have not been answered yet.It was decided that the issue raised in the document on how to use a list of endpoints which is revised post approval, will be discussed further at CA level. The SECR will open a Newsgroup for comments in writing after the meeting.

7.4 Draft BPC opinions on DDAC and ADBAC for PT 3 and 4

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

The eCA briefly introduced the case and indicated that the assessment of DDAC and ADBAC–BKC for PT 3 and 4 has already been discussed and agreed at the BPC-28. Then, SECR returned it to the eCA for the assessment of the ED properties. The applicant submitted the ED assessment in November 2018 and the eCA revised it according to the conclusions of WG-II-2020. The eCA indicated that they also added few amendments in the assessment report that were requested at BPC-28.

The discussion focussed then on the comments on the assessment report and the draft BPC opinion, as included in the open issues table and on the eCA's responses to them.

One outstanding issue concerned the submitted OECD 307 study on biodegradation in soil. This study was submitted during the peer review process and, in accordance with BPC procedures, it was not considered for the environmental risk assessment and can according to some members not be included in the List of Endpoints. Some BPC members requested that the study still needs to be peer reviewed in the ENV WG for both substances. Based on the results of the peer review, the List of Endpoints can be subsequently amended similar to the process followed for post approval data requested in section 2.5 of the BPC opinion.

A discussion took place about regarding the acceptability of an open access analytical method for the analysis of DDAC or ADBAC/BKC residues in various matrices of animal origin. Additional validation data are needed because this method is not validated in the meaning of the BPR. After a consultation with EFSA – based on which it was clarified by the Chair that EFSA has not requested nor evaluated such an analytical method – it was concluded that this requirement remains. This should be submitted at post approval stage as indicated in section 2.5 of the opinion. The Commission expressed regrets that this point was not addressed by the applicant and the eCA although it was already identified during the first discussions in the BPC in 2018, and called the applicant to submit the relevant information without additional delays.

More generally, the Commission invited all eCAs to be careful about missing analytical methods which is a recurrent issue in active substancs dossiers, and invited them to already request missing data during the examination of the active substances.

One item concerned the outcome of the environmental risk assessment: here one member stated that although there is at least one safe use identified there is still a need to check the calculations performed for PT 3. This would be beneficial for the product authorisation process. It was decided that there will be a consultation between the eCA, the member, the applicant and ECHA experts to carry out this check.

All the issues indicated in the open issues table were discussed and agreed by the Committee. The assessment reports were agreed and the BPC opinions for DDAC and ADBAC–BKC for PT3 and 4 were adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 20 November 2020.

- **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 27 October 2020 and publish it on the ECHA website.

7.5 Draft BPC opinion on the renewal of creosote for PT 8

The Chair welcomed the applicant. The ASOs were allowed to be present during the discussion. The discussion focussed on the items included in the open issues table regarding the comments on the assessment report and the draft BPC opinion.

The eCA (PL) briefly introduced the renewal application for creosote PT8 and explained that the current Renewal Assessment Report (RAR) is a combination of extracted sections from the first approval Assessment Report (AR) by the SE CA, the evaluation performed by UK CA before Brexit and the revision by PL after the WG I 2020. The Chair added that the focus of the BPC-36 discusssion is on the risk assessment conclusions and the conditions for the renewal of approval (Opinion Section 2.3). Overall, the reporting is still incomplete since to date the analysis of suitable alternatives has not been provided by the eCA. A second BPC discussion is scheduled for BPC-37 in December 2020 with the objective to adopt the opinion. The Chair reminded about the strict timelines for the creosote renewal process as the expiry date of renewal is in October 2021 after already a second extension of the deadline.

All the open issues related to RAR were discussed and conclusions/action points were agreed. Intensive discussions took place related to the open issues on the human health risk assessment:

(1) Use of terms “tolerable” vs “acceptable”: In accordance with the BPR Guidance Vol III Parts B+C the term “tolerable” should be used for the hazard characterisation of non-threshold genotoxic carcinogens. However, in accordance with BPR Article 19, the outcome of the assessment has to indicate if a specific use or scenario will not result in unacceptable effects which is expressed in the opinions normally as (un)acceptable risk. Overall, there is a need to use harmonised terminology for non-threshold carcinogens. It was suggested that in the RAR and opinion the outcome of the quantitative risk assessment should be presented and an explanatory text can be added to clarify the residual cancer risk involved (analoguous to the PEC/PNEC comparison for environmental assessment and additional argumentation with regards to PBT/vPvB properties).

(2) Revision of the DMEL value for workers: At HH WGI2020, the need to revisit the derivation of DMEL value for workers was clearly indicated. The eCA explained that after investigating the currently available information, they considered that the value proposed in the first approval AR and agreed at TM is still valid. Therefore, no re-calculation was performed by the eCA after the WG. It was pointed out by a number of members that the issue is still open and agreement is needed at HH WG level. As a follow-up action, SECR will provide a proposal on the DMEL revision which will be discussed in an ad hoc meeting. The HH assessment will be revised based on the agreed DMEL value.

(3) Derivation of a DMEL value for the general public: in principle, a DMEL for the general public should be determined to address the identified potential secondary exposure. However, considering the already identified risk for professional users and the strict conditions of use required, it was commented that derivation of a DMEL general public will not provide added value to the decision making process. Instead, a statement should be

included in the RAR and opinion to explain why a DMEL for general public was not derived. COM reminded that a clear conclusion of the risk assessment is nevertheless required (acceptable or unacceptable effects/risks).

The main open items related to APCP section of the RAR were discussed:

(1) Information requirement on the five batch analysis (5BA): The eCA explained the background and problems related to the 5BA information, for instance the difficulties in the identification of the individual constituents of creosote which is an UVCB substance. In their evaluation, the eCA concluded that Certificate of Analysis (CoA) will be sufficient to confirm the specification for creosote. SECR reminded that currently a data gap exists since the information requirement has not been properly fulfilled. A discussion took place on how to deal with the current situation considering the timelines of the creosote renewal process. The Commission expressed concerns that this point has not yet been solved in the renewal process, and called the applicant, the eCA and ECHA to addresss the matter. As a follow-up action, the eCA and applicant in consultation of SECR will look into the possibility to still fulfil the 5BA information requirement before the BPC meeting in December.

(2) Residue definition and validation of analytical methods: an agreement of the APCP WG on these points is still lacking. As a proposal from one of the members, it was suggested to base the residue defition on a selected number of PAH compounds. Monitoring methods for these compounds are available but so far sufficient information on the validation has not been provided by the applicant. It was underlined that the information requirement has to be fulfilled even for UVCB substances. The Commission expressed concerns that there are still issues with analytical methods although being already at the renewal process, and called the applicant, the eCA and ECHA to addresss the matter. As a follow-up action, the eCA should provide a proposal for the residue definition for the relevant matrices with the aim to finalise it before the December BPC meeting.

Due to time limitations at the meeting, only some selected open issues on the draft opinion were discussed. There was support from some of the members to a proposal on the conditions of storage of creosote treated articles, and the respective labelling requirements. Regarding the proposed labelling requirements on the placing on the market of treated wood, COM reminded of past discussion in the CA meeting on the limits of the BPR in relgulating treated articles, and noted that the interface between BPR and REACH needs to be further investigated.

Due to the identified hazards leading to exclusion criteria and the lack of data on certain critical endpoints (genotoxicity, ED assessment), one member would support the renewal of approval only for exceptional uses and applying the maximum RMMs. In addition, restrictions to the trade within the EU of treated articles was suggested where it was highlighted that a harmonised approach is important, also from an industry perspective.

Overall, a major revision of the draft opinion and RAR was expected by the members before it will be possible to adopt the opinion. Importantly, a clear outcome of the human health and environmental assessment is required for each use. For instance, at the moment the situation of brushing and dipping applications seems unclear. Furthermore, a unambiguous overall conclusion on the renewal proposal for each evaluated use should be included in the revised opinion. A proposal for harmonised restrictions for treated articles is expected. A clear outcome should be included with regards to potential secondary exposure via food residues.

Actions:

- **Rapporteur:** to revise the draft renewal assessment report and draft opinion in accordance with the discussions in the BPC and submit to the SECR by 25 October 2020.

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

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

The involved evaluating CA Italy informed the meeting that they accepted the post approval data submitted by the applicant. This was agreed by the meeting.

Actions:

- **Member (IT):** to forward the revised assessment report with the List of Endpoints to the SECR by 20 November 2020.

7.6.4. Copper pyrithione for PT 21

The involved evaluating CA Sweden informed the meeting that they accepted the post approval data submitted by the applicant. The evaluation performed was agreed by the meeting.

Actions:

- **Member (SE):** to forward the revised assessment report with the List of Endpoints to the SECR by 20 November 2020.

7.6.5. Salicylic acid for PT 2, 3 and 4

The involved evaluating CA The Netherlands informed the meeting that they accepted the post approval data submitted by the applicant. The evaluation performed was agreed by the meeting.

Actions:

- **Member (NL):** to forward the revised assessment report with the List of Endpoints to the SECR by 20 November 2020.

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 authorisation, and invited the concerned eCAs to take decision on the acceptance and validation of applications submitted already a long time ago. Not included in the table are four new applications for UA submitted in 2020 which substitute the cases for which UK was the eCA. Also not shown are seven UA applications that were rejected as they contained active substance that have not been approved yet. For the UA-BBP cases no progress is reported as the reference cases have not bene approved yet.

Ad ii) ECHA has written a letter to all competent authorities requesting a planning for active substance and union authorisation cases. Not all competent authorities have submitted their input yet, therefore an overview will be presented during next BPC. Preliminary analysis shows that the majority of union authorisation applications will not be finalised within three years following active substance approval.

New Interact functionalities will be launched in the course of next year: organisation of meetings and collaborations on documents (e.g. open issue table). The BPC will be updated on these developments in the future. BPC members and alternates should check whether they have access to Interact and if not to arrange they will obtain access. Other users (such as observers to the BPC, BPC WG members etc.) will also get access to Interact early next year.

Linguistic check of the SPC remains an issue and member states are called to perform the checks and to comply with the deadlines. It is noticed that an increasing number of member states are not checking the linguistic versions, are not doing it in time and do not check back with the applicant. It is important that this improves as the unchecked SPCs will be forwarded to the Commission and will therefore form the basis for the labels of the products on the national markets.

The Commission supported the concerns about progress of the Union Authorisation cases and of the linguistic checks of the SPC. Noted that if a dossier is incomplete, a non-authorisation decision should be taken rather than delaying the process. COM reminded that if after adoption mistakes are identified in any linguistic version, authorisation process will be further delayed.

Actions:

- **SECR**: to upload the presentation to S-CIRCABC.
- **All members and alternate members** to check whether they have access to Interact. If not, to arrange with their local User Administrator to get access to Interact.

8.2 Working procedure for Union authorisation applications

The SECR introduced the main changes in the new proposal for the working procedure for Union authorisation applications:

- Clarification that the eCA is responsible for communication with the applicant in the peer review phase. Further clarification that the eCA should update the applicant on progress of ad hoc follow up discussions.
- Information on how to handle comparative assessment reports.
- Footnote on commenting period for applicants vs commenting according to Article 44(1).
- Clarification on applicants possibility to re-open closed points for discussion prior to the Working Groups.

One member informed whether we are moving towards R4BP rather than Circabc for the making available of documents. Also would like to know whether communication in trilateral phase should be done via email. It would be good to have a single channel of communication.

ECHA clarified that indeed the idea is to phase out Circabc and to move towards R4BP and Interact. This will be reflected in future revisions of the working procedures. Direct communication via email in trilaterals may be possible, it should be clear that confidential information can't be shared via email.

The changes in the document were agreed with a slight wording revision for the second bullet point above to clarify that the comments from the applicant should be addressed, but not necessarily meaning that the changes proposed by the applicant are incorporated into the assessment.

In step 7 it is clarified that trilaterals containing non-confidential information can be done via email.

In step 14 it is clarified that the applicant may only include issues in the discussion table that were raised previously.

In step 43 it is clarified how the Commission will be informed about the upload of documents in R4BP.

Actions:

- **SECR**: to publish the revised working procedure on the BPC S-CIRCABC IG and the ECHA website.
- **SECR**: to present the new functionalities of Interact in the implications on the processes during the BPC meeting in December.

8.3 Article 75(1)(g) request received on an Union authorisation application for a biocidal product family containing CMIT/MIT

An Article 75(1)(g) request on an Union authorisation application for a biocidal product family containing CMIT/MIT was received by ECHA. The SECR informed the BPC about the request.

8.4 Consultation on an Union authorisation application for a biocidal product family containing CMIT/MIT

SECR informed the BPC on an Union authorisation application for a biocidal product family containing CMIT/MIT which could not be resolved at the Working Groups.

Actions:

- **All members**: to reflect on the issue with the experts back home and to prepare for the discussion during next BPC

8.5 Draft BPC opinion on am Union authorisation application for a biocidal product containing clothianidin and pyriproxyfen

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

The following issues were discussed and agreed upon:

- In the PAR, section 2.2.3 will be amended by the eCA and the agreed waiver will be moved to the 'Results' column. It was noted that there are different approaches between the eCAs how some information is presented in the PAR, e.g. as the applicant view accompanied by eCA remarks or just as the outcome of the evaluation/agreements made at earlier stages of the peer-review phase. This will be flagged for further investigation by the SECR in order to have a harmonised approach followed by all eCAs.
- The following RMMs will be added to the SPC:
  - *Inform the registration holder if the treatment is ineffective;*
  - *Spills and residues containing the product need to be removed as chemical waste.*
- The concentrations of SoC will be removed from section 2.1.a) of the BPC opinion.

As regards to the non-active substances with indication of having potential ED properties, the BPC decided to keep the indication in the opinion without disclosing the name of the substance. The Commission made clear that this situation is not satisfactory and not aligned with the decision supported by Member States in the Standing Committee to have the name of substances having the indication of potential ED properties publicly available in the Union authorisation decisions. On request of the Commission the eCA clarified whether for these non-active substances the applicant requested confidentiality and the outcome of the analysis of such a request. The eCA pointed out that the information on these non-active substances had been placed in the confidential part of the PAR as it is current practice for non-active substances not identified as substance of concern at most authorities. The Commission stated that this practice is not aligned with the provisions in the BPR on confidentiality and needs to be amended.

In addition the members from SE and FI informed that due to national policies concerning active substances used in PT 18 or 19 biocidal products which are toxic to bees, they will likely request to adjust the conditions of this UA for their territories to add a specific labelling provision for the protection of bees due to the presence of clothianidin. The Commission asked for a discussion on the SE request, and indicated that the working group Environment of the BPC developed a paper for the Coordination Group describing

several options for having warning sentences for bees. On request of the COM the eCA confirmed that based on the outcome of the risk assessment, no risk to bees was identified by the use of the product as intended.The members from SE and FI will inform the Commission whether they will proceed with asking for a derogation in accordance with Article 44(5) of the BPR. The Commission further highlighted the need for coherence with the on-going discussion in the Coordination Group about the relevance, as well as the drafting, of such sentence aiming to address the protection of bees.

The PAR, SPC and BPC opinion were adopted by consensus.

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 26 October 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 2 November 2020.

9. Any Other Business

9.1 Revision ECHA Guidance Volume III Human Health Information Requirements

SECR informed that the document provided to the BPC was already submitted to the HH WG and BPC in June 2020, but the item was not discussed at the June BPC. The guidance revision was triggered by the change in information requirements, where the largest changes concern the human health part, resulting in the highest priority in guidance revision.

In addition to the revisions that are necessary due to changes in information requirements, ECHA will also update the guidance with regard to scientific development. To identify as far as possible all such issues, the HH WG members and ASOs were requested to provide input during summer 2020. Input was received from DE, DK, EL, ES, FR and NL.

As for the earlier guidance development, the procedure will not include a consultation step with the BPC, considering that the most appropriate MSCA forum to be consulted is the HH WG that is part of the PEG. The HH WG will be kept fully updated on the developments. The discussions on the guidance will however take place via the PEG, to which the WG members are invited to participate.

The drafting has recently started. As the next steps, the Partner Expert Group (PEG) will be formed early 2021 and the PEG consultation is expected to be launched in May 2021. The PEG meeting is expected to take place in October 2021, followed by launching the COM and CA consultation by the end of 2021. Publication of the final guidance is foreseen to take place in March 2022.

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 36th meeting of BPC
6-8 October 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-35	
The revised version of the minutes of BPC-35 was agreed as proposed.	**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 **16 October 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.	**-**
7.1.2. Working procedure for active substance approval	
The BPC discussed and agreed on the revised working procedure.	**SECR**: to publish the revised working procedure on the BPC CIRCABC IG and the ECHA website.
7.2 Article 75(1)(g) requests received:	
7.2.1. Evaluation of the level of the risks for human health and for the environment of DBNPA used in biocidal products of product type 4	
The BPC discussed the request and agreed that the member from DK will act as the rapporteur.	**SECR:** to coordinate this request with the one under agenda item 7.2.2.
7.2.2. Evaluation of the level of the risks for human health and for the environment of cyanamide used in biocidal products of product types 3 and 18	
The BPC discussed the request and agreed that the member from DE will act as the rapporteur.	**SECR**: to coordinate this request with the one under agenda item 7.2.1.
7.2.3. Evaluation of the availability and suitability of alternatives to boric acid and disodium tetraborate pentahydrate for PT8	
The BPC discussed the request and agreed that the member from NL will act as the rapporteur.	**-**
7.3 List of Endpoints for environmental exposure assessment for peracetic acid (PAA) and hydrogen peroxide	
The BPC discussed the document. A future discussion on the issue will take place at CA level.	**-**
7.4 Draft BPC opinions on DDAC and ADBAC for PT 3 and 4	
The BPC adopted by consensus the opinions for the approval of the active substance PT combination.	**Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR by **20 November 2020.** **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 **20 November 2020** and publish them on the ECHA website.
7.5 Draft BPC opinion on the renewal of creosote for PT 8	
The BPC discussed the opinion of the active substance/PT combination.	**Rapporteur:** to revise the draft renewal assessment report and draft opinion in accordance with the discussions in the BPC and submit to the SECR by **25 October 2020.**
7.6 Revised Assessment Report following the submission of data after active substance approval:	
7.6.1. Active chlorine release from sodium hypochlorite for PT 1 – 5	
The member from IT informed the BPC about the evaluation of the data submitted after the approval.	**Member (IT):** to forward the revised assessment report with the List of Endpoints to the SECR by **20 November 2020.**
7.6.2. Active chlorine release from calcium hypochlorite for PT 2 - 5	
The member from IT informed the BPC about the evaluation of the data submitted after the approval.	**Member (IT):** to forward the revised assessment report with the List of Endpoints to the SECR by **20 November 2020.**
7.6.3. Active chlorine release from chlorine for PT 2 and 5	
The member from IT informed the BPC about the evaluation of the data submitted after the approval.	**Member (IT):** to forward the revised assessment report with the List of Endpoints to the SECR by **20 November 2020.**
7.6.4. Copper pyrithione for PT 21	
The member from SE informed the BPC about the evaluation of the data submitted after the approval.	**SECR:** to consult internally if there is a need to re-submit the revised assessment report with the List of Endpoints by SE. If so: **Member (SE):** to forward the revised assessment report with the List of Endpoints to the SECR by **20 November 2020.**
7.6.5. Salicylic acid for PT 2, 3 and 4	
The member from NL informed the BPC about the evaluation of the data submitted after the approval.	**Member (NL):** to forward the revised assessment report with the List of Endpoints to the SECR by **20 November 2020.**
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 Working procedure for Union authorisation applications	
The BPC discussed and agreed the revised working procedure.	**SECR**: to publish the revised working procedure on the BPC CIRCABC IG and the ECHA website.
8.3 Article 75(1)(g) request received on an Union authorisation application for a biocidal product family containing CMIT/MIT	
The BPC discussed the request and agreed that the member from FR will act as the rapporteur.	**-**
8.4 Consultation on an Union authorisation application for a biocidal product family containing CMIT/MIT	
The BPC was informed about this issue.	**-**
8.5 Draft BPC opinion on am Union authorisation application for a biocidal product containing clothianidin and pyriproxyfen	
The BPC adopted by consensus 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 **26 October 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 **2 November 2020**.
Item 9 –Any other business	
9.2 Revision ECHA Guidance Volume III Human Health Information Requirements	
The BPC took note on the document.	-

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Part III - List of Attendees

Members	DE LA USADA MOLINERO Eduardo (ES)
BALDASSARRI Lucilla (IT)	EHNI Markus (DE)
BORGES Teresa (PT)	GKILPATHI Dimitra (EL)
BROVKINA Julija (LV)	GÓRECKI Roman (PL)
BUEHLER Dominique (CH)	HAMALAINEN Anna-Maija (FI)
CARBERRY Stephen (IE)	HORCZYCZAK Anna (PL)
CEBASEK Petra (SI)	HUIZING Tjaart Jan (NL)
GONZALEZ MARQUEZ Maria Luisa (ES)	IAKOVIDOU Mary (SE)
GREGERSEN Nina Falk (DK)	IZQUIERDO MOYA Inmaculada (ES)
HADJIGEORGIOU Andreas (CY)	KALKERS Lucas (NL)
HAHLBECK Edda (SE)	KRAFTE Kristine (LV)
HAKAITE Palmira (LT)	MUIJS Barry (NL)
JAGER Stefanie (DE)	NIEMINEN Timo (FI)
JOHN Nina (AT)	PUERGY Reinhild (AT)
KOIVISTO Sanna (FI)	RIFFAUT Lea (FR) *
LANS Martine (NL)	RUIZ LÓPEZ Elena Fuensanta (ES)
MERISTE Anu (EE)	RZODECZKO Helena (PL)
MIKOLAS Jan (CZ)	VÄLIMÄKI Elina (FI)
MIKOLASKOVA Denisa (SK)	VUORENSOLA Katariina (FI)
RANDALL Marit (NO)	WEINHEIMER Viola (DE)
VAGIAS Vasileios (EL)	WELTEN Angelique (NL)
VRHOVAC FILIPOVIC Ivana (HR)	WIŚNIEWSKA Iwona (PL)
Alternate members	**European Commission**
COLLET Romy (FR)	CAINZOS GARCIA Marta (DG SANTE)
ENSCH Svenja (LU)	CHATELIN Ludovic (DG SANTE)
JARRETY Helene (BE)	GKINIS Georgios (DG SANTE)
SZENTGYORGYI Timea (HU)	NAGTZAAM Martinus (DG SANTE)
Advisers	
BOS Carina (NL)	**Invited experts**
CATALDI Lucilla (IT)	HUSZAL Sylwester (PL)
COUGNON Thomas (BE)	
COX Nina (NL)	

Accredited Stakeholder Observers	ECHA Staff
CINGOTTI Natcha	RUGGERI Laura
DREVE Simina-Virginia	STASKO Jolanta
KJELLBERG Håkan	SZYMANKIEWICZ Katarzyna
MIHAI Camelia	VAN DE PLASSCHE Erik
	VAN DER LINDEN Sander
Applicants	VAN GALEN Joost
Calcium Hypochlorite Biocides Registration Group Sodium Hypochlorite Biocides Registration Group Chlorine Registration Biocides Group	
Creosote Council. Europe (CCE)	**Apologies**
European Quat Consortium (EQC)	MT
Sumitomo Chemical (UK) Plc	RO
US ISC	
ECHA Staff	
AIRAKSINEN Antero	
CARLON Claudio	
ESTEVAN MARTINEZ Carmen	
HONKA ANNI	
JARDIN Helene	
KENIGSWALD Hugues	
KREBS Bernhard	
KURONEN Terhi	
LAITINEN Jaana	
PAPADAKI Paschalina	
PRIHA Outi	

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-36

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-36 meeting

Meeting documents		
Agenda Point	**Number**	**Title**
2	BPC-A-36-2020_rev1	Draft agenda
4	BPC-M-35-2020	Draft minutes from BPC-35
5.1	-	Administrative issues and report from the other Committees
6.1	BPC-36-2020-01 BPC-36-2020-02 BPC-36-2020-03 BPC-36-2020-04	BPC Work Programme for active substance approval, Union authorisation, ED assessment and outlook for BPC
7.1	BPC-36-2020-05	7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval
	BPC-36-2020-06	7.1.2. Working procedure for active substance approval
7.2	BPC-36-2020-07	7.2.1. Evaluation of the level of the risks for human health and for the environment of DBNPA used in biocidal products of product type 4
	BPC-36-2020-08	7.2.2. Evaluation of the level of the risks for human health and for the environment of cyanamide used in biocidal products of product types 3 and 18
	BPC-36-2020-09	7.2.3. Evaluation of the availability and suitability of alternatives to boric acid and disodium tetraborate pentahydrate for PT8
7.3	BPC-36-2020-10	List of Endpoints for environmental exposure assessment for peracetic acid (PAA) and hydrogen peroxide
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
	BPC-36-2020-17	7.6.4. Copper pyrithione for PT 21
	BPC-36-2020-18	
	BPC-36-2020-19	7.6.5. Salicylic acid for PT 2, 3 and 4
	BPC-36-2020-20	

	BPC-36-2020-21		
8.2	BPC-36-2020-22	Working procedure for Union authorisation applications	
8.3	BPC-36-2020-23	Article 75(1)(g) request received on an Union authorisation application for a biocidal product family containing CMIT/MIT	
9.1	BPC-35-2020-25	Revision ECHA Guidance Volume III Human Health Information Requirements	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.4	BPC-36-2020-11A	DDAC PT 3	Draft BPC opinion
	BPC-36-2020-11B		Assessment report
	BPC-36-2020-11C		Open issues
	BPC-36-2020-12A	DDAC PT 4	Draft BPC opinion
	BPC-36-2020-12B		Assessment report
	BPC-36-2020-11C		Open issues
	BPC-36-2020-13A	ADBAC PT 3	Draft BPC opinion
	BPC-36-2020-13B		Assessment report
	BPC-36-2020-13C		Open issues
	BPC-36-2020-14A	ADBAC PT 4	Draft BPC opinion
	BPC-36-2020-14B		Assessment report
	BPC-36-2020-13C		Open issues
7.5	BPC-36-2020-15A	Renewal of creosote PT 8	Draft BPC opinion
	BPC-36-2020-15B		Renewal assessment report
	BPC-36-2020-15B1		Conf Annex to Renewal assessment report MS only
	BPC-36-2020-15C		Open issues
	BPC-36-2020-15D		Peer review summary
	BPC-36-2020-15E		Addition to Overall conclusions
	BPC-36-2020-15F		Peer review summary – NL comments
8.5	BPC-36-2020-24A	UA: biocidal product containing clothianidin and pyriproxyfen	Draft BPC opinion
	BPC-36-2020-24B		SPC
	BPC-36-2020-24C		PAR
	BPC-36-2020-24C1		Conf Annex to PAR
	BPC-36-2020-24D		Open issues
	BPC-36-2020-24E		Comparative assessment
	BPC-36-2020-24F		ED screening table

25 September 2020
BPC-A-36-2020_rev1

Draft agenda

36th meeting of the Biocidal Products Committee (BPC)

6 - 8 October 2020

Meeting is held virtually via WebEx

Starts on 6 October at 10:30, ends on 8 October at 16:00

The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-36-2020

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-35

BPC-M-35-2020

For agreement

5. – Administrative issues

5.1. Administrative issues

For information

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

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-36-2020-01; BPC-36-2020-02; BPC-36-2020-03; BPC-36-2020-04

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-36-2020-05

For information

7.1.2. Working procedure for active substance approval

BPC-36-2020-06

For information

7.2. Article 75(1)(g) requests received:

7.2.1. Evaluation of the level of the risks for human health and for the environment of DBNPA used in biocidal products of product type 4

BPC-36-2020-07

For information

7.2.2. Evaluation of the level of the risks for human health and for the environment of cyanamide used in biocidal products of product types 3 and 18

BPC-36-2020-08

For information

7.2.3. Evaluation of the availability and suitability of alternatives to boric acid and disodium tetraborate pentahydrate for PT8

BPC-36-2020-09

For information

7.3. List of Endpoints for environmental exposure assessment for peracetic acid (PAA) and hydrogen peroxide

BPC-36-2020-10

For information and discussion

7.4. Draft BPC opinions on DDAC and ADBAC for PT 3 and 4

Previous discussion(s): WG-II-2020; BPC 28; WG-V-2017

DDAC PT 3: BPC-36-2020-11A, B, C

DDAC PT 4: BPC-36-2020-12A, B, C

ADBAC PT 3: BPC-36-2020-13A, B, C

ADBAC PT 4: BPC-36-2020-14A, B, C

For adoption

[†] 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).

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

Previous discussion: WG–I-2020

BPC-36-2020-15A, B, C

For discussion

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

7.6.1. Active chlorine release from sodium hypochlorite for PT 1 - 5

BPC-36-2020-16

For agreement

7.6.2. Active chlorine release from calcium hypochlorite for PT 2 - 5

BPC-36-2020-16

For agreement

7.6.3. Active chlorine release from chlorine for PT 2 and 5

BPC-36-2020-16

For agreement

7.6.4. Copper pyrithione for PT 21

BPC-36-2020-17, BPC-36-2020-18

For agreement

7.6.5. Salicylic acid for PT 2, 3 and 4

BPC-36-2020-19, BPC-36-2020-20, BPC-36-2020-21

For agreement

8. – Union authorisation[**]

8.1 Update on Union authorisation

For information

8.2 Working procedure for Union authorisation applications

BPC-36-2020-22

For agreement

8.3 Article 75(1)(g) request received on an Union authorisation application for a biocidal product family containing CMIT/MIT

BPC-36-2020-23

For information

[**] 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).

8.4 Consultation on an Union authorisation application for a biocidal product family containing CMIT/MIT

For information

8.5 Draft BPC opinion on am Union authorisation application for a biocidal product containing clothianidin and pyriproxyfen

Previous discussion: WG-II-2020

BPC-36-2020-24A, B, C, D

For adoption

9. - Any other business

9.1 Revision ECHA Guidance Volume III Human Health Information Requirements

BPC-36-2020-25

For information

10. - Action points and conclusions

Provisional time schedule for the

36th meeting of the Biocidal Products Committee (BPC)

Virtual meeting via WebEx

6 October 2020: starts at 10:30; 8 October 2020 ends at 16:00

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 6 October: (starts at 10:30, ends at 17:00)

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
	7.1.2. Working procedure for active substance approval
Item 7.2	Article 75(1)(g) requests received:
	7.2.1. Evaluation of the level of the risks for human health and for the environment of DBNPA used in biocidal products of product type 4
	7.2.2. Evaluation of the level of the risks for human health and for the environment of cyanamide used in biocidal products of product types 3 and 18
	7.2.3. Evaluation of the availability and suitability of alternatives to boric acid and disodium tetraborate pentahydrate for PT8
Item 7.3	List of Endpoints for environmental exposure assessment for peracetic acid (PAA) and hydrogen peroxide
Item 7.4	Draft BPC opinions on DDAC and ADBAC for PT 3 and 4

Wednesday 7 October: (starts at 10:30, ends at 17:00)

Item 7.5	Draft BPC opinion on the renewal of creosote for PT 8
Item 7.6	Revised Assessment Report following the submission of data after active substance approval:
	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
	7.6.4. Copper pyrithione for PT 21
	7.6.5. Salicylic acid for PT 2, 3 and 4

Thursday 8 October: (starts at 10:30, ends at 16:00)

Item 8.1	Update on Union authorisation
Item 8.2	Working procedure for Union authorisation applications
Item 8.3	Article 75(1)(g) request received on an Union authorisation application for a biocidal product family containing CMIT/MIT
Item 8.4	Consultation on an Union authorisation application for a biocidal product family containing CMIT/MIT
Item 8.5	Draft BPC opinion on am Union authorisation application for a biocidal product containing clothianidin and pyriproxyfen
Item 9	AOB
	9.1 Revision ECHA Guidance Volume III Human Health Information Requirements
Item 10	Action points and conclusions

End of meeting

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