15 June 2021

BPC-M-38-2021

Minutes of the 38th meeting of the Biocidal Products Committee (BPC)

2-5 March 2021

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chair of the Biocidal Products Committee (BPC) welcomed the participants to the 38th BPC meeting which took place as a virtual meeting via Webex.

Regarding the BPC membership, the Chair stated the following changes: there is a new appointed BPC member from Poland; Helena Rzodecko and a new appointed alternate BPC member from Poland; Sylwester Huszal. There is also a new appointed BPC member from Belgium; Helene Jarrety and a new appointed alternate BPC member from Belgium; Thomas Cougnon. Also Estonia has appointed a new alternate BPC member; Helen Sulg.

The Chair then informed the BPC members of the participation of 27 members, including three alternate members.

21 advisers and 8 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-38-2021_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-37

The revised draft minutes from BPC-37 (BPC-M-37-2020), incorporating the comments received, were agreed.

The Chair noted that all actions from BPC-37 have been carried out.

The Chair further informed the meeting on the following: with respect to the adopted opinion on diamine it was decided in consultation with the Commission to consult the BPR Subgroup of the Forum (BPRS) on the enforceability of a label restriction related to the number of cycles in a wood treatment plant using vacuum pressure impregnation. This consultation will feed into the decision making process at the Standing Committee where a first discussion will take place the week after BPC-38.

Actions:

- **SECR:** to upload the agreed minutes from BPC-37 to the BPC S-CIRCABC IG and to the ECHA website after the meeting.

5. Administrative issues

5.1 Changes in ECHA biocides organisation

The SECR informed the meeting on the changes within ECHA on the biocides organisation.

5.2 Feedback received from the BPC members' interviews

The Chair thanked BPC members for their valuable contributions in the interviews which he carried out in the beginning of 2021 and presented a short summary of the feedback received.

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 2021 the planned opinions are listed in the "Outlook" document. The Chair asked members to note that for active substance approval (AS) and Union authorisation (UA) a dossier is listed only if the dossier is submitted for the corresponding process flow by the evaluating Competent Authority (eCA). Consequently, currently 4 opinions are scheduled for UA and 10 for AS for 2021. It is expected that both for AS and UA a substantial increase will occur for PF 40 and 41. Overall, it is expected that the total number of adopted opinions will be comparable to 2020 meaning that the workload for 2021 will be manageable.
- For 2022 however an increase is expected for both AS and UA. The Chair referred to discussions at the CA meeting next week where ECHA will report on the Active Substance Action Plan (ASAP) and to the presentation under agenda item 8.1.
- Furthermore, 3 opinions following an Article 75(1)(g) request are scheduled for 2021 and one following an Article 38 request. More Article 38 requests are expected.

- Reference was made to the status of ED assessment for information purposes. 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.

The Chair asked the eCAs being rapporteur for active substances or Union authorisations scheduled for discussion at the June 2021 BPC meeting (BPC-39), to confirm this planning to the SECR by 3 May 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 ASAP, 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., This situation concerns 8 Member States (France, Greece, Italy, Malta, the Netherlands, Poland, Spain, Sweden). 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 as ED data is part of the data requirements, but it is still investigating whether there could be possibilities to move forward without such an assessment on a case-by-case basis. Member States should therefore continue requesting data to assess ED properties on such active substances.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by 12 March 2021.

6.2 Outlook BPC 2014 – 2020

The Chair presented an overview of the BPC achievements over the last years.

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 that no changes were introduced in the document compared to the version presented at BPC-37.

Actions:

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

7.1.2 Instruction manual on preparing a BPC opinion on active substance approval and renewal in case of a full evaluation and corresponding opinion templates

The SECR presented the documents mentioning that: i) the instruction manual was revised including the experience since the first version agreed at BPC-15; ii) the manual now also includes renewal, however limited to 'full evaluation'; iii) the opinion template was revised for the first approval and one developed for renewal, again limited to 'full evaluation'. For a renewal process with the shorter timeline of 90 days the opinion format will have to be case-by-case. The documents were agreed with some revisions. It was also noted that the need to improve the sections of the BPC opinions related to the analysis of alternatives on active substance meetings the exclusion or subsitution criteria is part of a larger discussion on the agenda of this meeting (item 9.1).

Actions:

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

7.2. – 7.5 Draft BPC opinions silver zinc zeolite, silver copper zeolite, silver zeolite and silver sodium hydrogen zirconium phosphate for PT 4

The Chair welcomed the applicant for this item as well as several representatives from EFSA. The ASOs were allowed to be present during the discussion. The Chair introduced the agenda items by stating the intention to adopt the opinions for silver zinc zeolite (SZZ), silver zeolite (SZ), silver copper zeolite (SCZ) and silver sodium hydrogen zirconium phosphate (SSHZP) for product type (PT) 4. The members were reminded that at BPC-27 the SECR informed that ECHA was requested by the Commission to consult with EFSA on the outcome of the human health risk assessment and to wait the adoption of these opinions until this consultation had taken place. The request was due to the interplay between the Biocidal Products Regulation and the regulation on Food Contact Materials (EU) No 1935/2004. The Chair informed further that the applicant had submitted a letter the day before the meeting, proposing concrete restrictions for the use of silver in polymers and water filters.

The SECR presented the joint EFSA – ECHA document (entitled: "Comparison of the evaluations performed on silver compounds used as biocidal active substances in food contact materials (FCM)"), as a result of the above mentioned consultation. This document was finalised in February 2020. Subsequently, it was discussed how this joint document should be reflected in the opinions. The Chair introduced a text proposal to be included into the BPC opinions explaining the EFSA - ECHA consultation and pointing out the main differences in the assessment. This text proposal was discussed and agreed by the BPC with some modifications. Several BPC members supported the proposal from the Chair to make the joint EFSA - ECHA document publicly available. It was decided that ECHA and EFSA would consult further on how the document will exactly be made available.

The rapporteur presented the opinions and explained that the risk assessment for SZZ was available to the applicant already in 2012, which showed unacceptable risk for the uses in polymers and water filters. Several times and specifically in 2016 the applicant was recommended by the rapporteur to provide additional data, for example on migration. The Chair pointed out that the opinions show unacceptable risks for polymers for all age

groups and for the water filters for infants and noted the non-approval proposals are similar to the versions discussed at BPC-27. It was at that time discussed whether mitigation of the risk would be possible for water filters with a specific label instruction addressing the age group at risk. The Chair noted the non-approval proposals for SCZ and SSHZP are also based on a lack of demonstration of efficacy.

The applicant confirmed that there are two uses: the use in polymers and in water filters. For the polymers, the applicant considered that the risk assessment had been done by using extreme values, which considered in isolation might be acceptable but together result in an over-conservative assessment. Safe use for water filters had been shown for all user groups apart for infants, where a small risk was identified to his views. The applicant proposed to restrict the use of impregnated water filters to commercial use, for instance in restaurants, which should be sufficient to mitigate the risk to infants. The applicant also pointed out the importance of the technology of activated carbon in water filters and to prevent bacterial growth on the filter by using the bacteriostatic effect of silver ions. It was later clarified that the water filters are not used in filters for residential use to filter tap water for consumption. The applicant stated that currently there is no replacement technology for such silver impregnated filters for commercial use in e.g. soda batteries. For polymers the applicant proposed, a restriction to use silvers only in polymers used to make ice equipment and cheese coatings by the applicant.

One member asked if the lack of efficacy for SCZ and SSHZP (for which only use in polymers was applied for) referred to bacteriostatic or bactericidal claims. The rapporteur explained that the example uses applied for by the applicant were vague and shifted over time. No study showed a fast bactericidal effect whereas a bacteriostatic effect was considered not sufficient to protect consumers from cross-contamination. Furthermore, tests showed that the presence of organic material reduced the efficacy of silver. Several members agreed that the new claims to only make use of polymers in ice equipment and cheese coatings were made too late in the process, and no assessment is available related to these specific uses.

The feasibility of risk mitigation measures for infants by using the water filter only in commercial environments like restaurants, was intensively discussed. Such a restriction for the product would not permit authorisation for the use to treat carbon water filters for residential use, and the water filter would be labelled with ‘For commercial use only; not for residential use’. The applicant explained that: i) the water filters are used to improve the water quality before consumption and to prevent clogging of the filter; and ii) are certified for a certain amount of filtered water. It was asked to which extent the water consumption of infants would need to be reduced in order for the use to be safe. It was explained that the amount of the infant’s daily consumption of filtered water would need to be reduced by around 50%. Several members expressed their doubts on the feasibility of the proposed restriction to use the water filters only in a commercial setting. Several members indicated that it cannot be excluded that infants are exposed via the consumption of filtered drinking water in restaurants and bars. This might be by customers of restaurants and bars bringing their infants with them but especially infants of the restaurant or bar owners. It was also noted that no information is available on the risk reduction potential of such a measure: data with respect to the in-house drinking water consumption of the general public versus outside the house (in for example restaurants and bars) and/or with respect to infants are lacking. Such data would allow to assess if the risk to infants can be mitigated to reduce the risk to acceptable levels. Further it was noted that there is no direct link between a warning given on the label of the treated filter

(i.e. indicating that the treated water filter is for use in commercial settings only) and the objective of the measure (i.e. the prevention of the consumption by infants of drinking water which has passed through an impregnated filter), and it was also noted that water cannot be labelled. The Commission pointed out that the BPR is referring to acceptable or unacceptable effects or risks, and a key question is to know whether the risk can be mitigated and reduced to acceptable levels. The Chairman confirmed that it would be relevant to mitigate the risk to an acceptable level. However, he referred also to the notion in the BPR of protection of vulnerable groups. In the end the proposed measure by the applicant was not supported by the majority of the members. Also no further suggestions for risk mitigation measures were brought forward.

Several comments relevant for all opinions were discussed:

- The applicant suggested to use a 2% application rate for the active substance in the water filters instead of 3% and mean values for the migration rate over the lifetime of the filter. It was clarified that a risk assessment based on a 2% application rate was not presented nor discussed at the Working Groups and that no efficacy data for the rate of 2% are available. Consequently, this suggestion was not supported.
- The applicant commented that data on migration into food simulants other than acetic acid were provided but not presented in the Assessment Report (AR). It was agreed that these data would be added.
- A proposal to include in all opinions an explanation why the acute exposure scenario was compared with the long-term reference value in the assessment was supported.
- It was agreed that uses not relevant for PT 4 should not be mentioned in the opinions but to clearly describe scenarios and uses assessed for PT4.
- Further is was agreed to align in section 2.2.1 the table in relation to the presentation of the ED properties as well as the text below the table with opinions adopted recently.

One comment relevant for the SCZ, SZ and SZZ opinions referred to the statement in section 2.3 on classification as aquatic chronic 1 preventing Annex I inclusion. It was agreed that the statement should be removed in order to harmonise with already adopted opinions under the assumption that this is not supported by Article 28 of the BPR. COM was requested to clarify this issue in regard to Article 28 and inform the BPC on the outcome.

All items in the open issues table relevant to **silver zinc zeolite** were addressed. COM noted that it should be indicated clearly in Section 2.3 that the biocidal product consists of 100% active substance.The BPC agreed on the Assessment Report and adopted by consensus the opinion on the non-approval of SSZ for PT 4. Two members abstained.

All items in the open issues table specifically relevant to **silver copper zeolite** were addressed. One comment referred to the use of water filter for which the applicant did not apply for. It was agreed that this use together with the related exposure scenarios should be removed. The BPC agreed on the Assessment Report and adopted by consensus the opinion on the non-approval of SCZ for PT 4. Two members abstained.

All items in the open issues table specifically relevant to **silver zeolite** were addressed. The BPC agreed on the Assessment Report and adopted by consensus the opinion on the non-approval of SZ for PT 4. Two members abstained.

All items in the open issues table specifically relevant to **silver sodium hydrogen zirconium phosphate** were addressed. One comment referred to the use of water filter for which the applicant did not apply for. It was agreed that this use should be removed. The BPC agreed on the Assessment Report and adopted by consensus the opinion on the non-approval of SSHZP for PT 4. Two members abstained.

The rapporteur noted after the adoption of the opinions that the evaluation has been overall very complex, partly due to lack of data and the use of read across. The rapporteur pointed out that there is no reservation in general from their perspective towards the use of silver as an active substance. However, the evaluations were complex and their questions and requests for additional data were often not sufficiently addressed by the applicant. The discussion today has shown that it is difficult to turn around a proposal in the last minute, and it would have been more successful to submit data and/or proposals at an earlier point in time. It was remarked that this is the first group of substances which is solely used for incorporation into polymers which are used to make treated articles of different matrixes, including polymers, where methodologies had to be developed during the evaluation process. The rapporteur would welcome support from other Member States, ECHA and COM in this complicated and challenging task to assess this large group of silver compounds. The rapporteur noted that there are no other Member States involved as rapporteur in the evaluation of in total 56 silver-containing active substance PT combinations.

The applicant thanked the BPC for considering his proposed restrictions for discussion. However, the applicant noted that although there is an extensive database on migration available, a safe use was not identified. The applicant regarded this mainly due to repeated consideration of extreme worst-case scenarios, which resulted in an overall very conservative assessment. The applicant expressed disappointment that not one safe use could be identified, such as the use in ice equipment or in water filters.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 16 April 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 23 March 2021 and publish it on the ECHA website.

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

7.6.1. PBO 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.

However, the evaluating CA confirmedthat still not all post approval data specified in section 2.5 of the BPC opinion have been submittedThe Commission urged the applicant and the evaluating CA to make progress on the matter.

7.6.2. Ampholyt for PT 2, 3 and 4

The involved evaluating CA Ireland 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 (IE):** to forward the revised assessment report with the List of Endpoints to the SECR by **16 April 2021.**

7.6.3. Bardap 26 for PT 8

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

Actions:

- **Member (IT):** to forward the revised assessment report with the List of Endpoints to the SECR by **16 April 2021.**

8. Union authorisation

8.1 Update on Union authorisation

An update on Union authorisation was given by the SECR.

Actions:

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

8.2 Instruction manual on preparing a BPC opinion on an Union authorisation application including the opinion template

The SECR presented the document: i) an instruction manual was prepared by the SECR based on the experience so far; ii) the template for the BPC opinion was revised giving some more guidance on the different sections of the opinion. The documents were agreed with some revisions.

Actions:

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

8.3 Draft BPC opinion on an Union authorisation application for a biocidal product family containing peracetic acid

The Chair welcomed the applicant. The stakeholders were allowed to be present during the discussion. The rapporteur briefly introduced the dossier related to a biocidal product family containing peracetic acid as active substance. The family is composed of 4 meta-SPCs. Several points were discussed during the meeting as listed in the open issue table, including those noted below.

A discussion took place on whether hydrogen peroxide and acetic acid, which act as non-active substances in the products of the family and are not considered as SoC, should be included in section 2.1 Qualitative and quantitative information on the composition of the SPC. It was considered that the knowledge of acetic acid and hydrogen peroxide is essential for proper use of biocidal products since these are part of the active substance and influence the equilibrium. Therefore, it was agreed that, these substances also need to be listed in section 2.1 of the SPC. The Chair noted that the same approach has to be followed for similar applications for Union as well as national authorisation.

The applicant questioned the proposed classification Acute Tox 4 (inhalation) for the products included in meta-SPCs 2 and 3. The rapporteur noted that the classification was presented and agreed during the Working Group Human Health meeting. It was agreed that: i) ECHA will look into the proposed classification for this endpoint after the meeting and consult with the rapporteur; ii) this issue would not prevent adopting the opinion.

The applicant disagreed with the proposed restriction of the room size for fogging applications, and proposed to link the room volume to a single fogging device as the current text prevents installing more devices for large rooms. In a response to the questions of the members, the rapporteur confirmed that, in the environmental risk assessment large rooms were considered, whereas for human health risk assessment the room size does not have an effect on the assessment since fogging should be performed without persons being present in the room (re-entrance is allowed only when a particular concentration of peracetic acid is reached). From an efficacy perspective, different views were expressed. However, one member noted that until now there has been no discussion and agreement on how to proceed if several devices are used for fogging. Since the validation phase is included, the BPC agreed to remove the restriction for the room sizefrom the title of the relevant uses, and include a note in section 5.1. “Instructions for use” of SPC that the volume is per application and per device.

A question was raised by a member whether the “original LoEP (List of Endpoints)” values agreed at active substance approval stage or the “amended LoEP” was used in the assessment. The rapporteur clarified that the “amended LoEP” was used. A member reminded about previous discussions at BPC and CA level. COM noted that discussions on this particular situation are on-going, and it is expected to be discussed in the following CA meeting. Thus, it was agreed that the PAR will not be amended, but this issue will be noted by the Chair when the opinion is submitted.

During the meeting the rapporteur presented an updated human health risk assessment for soaking activities since the minimum in-use concentration was changed. The modification was supported. However, it was noted that “relevant RPE” should be included in the SPC in line with the risk identified.

Several members noted that it needs to be ensured that the same information is reported consistently in all documents (BPC opinion, SPC and PAR).

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 reached at the BPC and as reflected in the open issue table. The BPC opinion was 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 19 March 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, draft SPC and final PAR to COM by 23 March 2021 and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by 16 April 2021.

9. Any Other Business

9.1 Dedicated session on analysis of alternatives

There were three presentations, each one followed by a discussion with questions, comments and or suggestions.

Firstly, the member from the Netherlands presented their evaluation of the analysis of alternatives under the pilot project for the borates (an Article 75(1)(g) request to evaluate the availability and suitability of alternatives to boric acid and disodium tetraborate pentahydrate for product type 8; active substances under renewal meeting the exclusion criteria). The following was reported: i) process; ii) sources of information used; iii) expertise needed; iv) workload of the experience; v) ending with conclusions and suggestions. The latter included: i) requirement for a clear description of the scope, requirements, criteria, roles and tasks; ii) to benefit from the REACH experience on the analysis of alternatives; and iii) to develop guidance and templates.

Secondly, ECHA presented the applications under REACH for authorisation and analysis of alternatives. This presentation also included some remarks on their experience on the above mentioned pilot project for borates, where they contributed by assisting with a stakeholder's survey to gather information. The most relevant aspects were: i) reponsabilities of the applicant; ii) development of two different documents: the analysis of alternatives and the socio-economic analysis; iii) pre-submission meetings with the applicant; and iv) network/consortium possibilities for SMEs. The latter might be considered for the biocides.

Thirdly, a presentation from ECHA on how to improve the analysis of alternatives under the BPR with short- and long-term suggestions for improving. The presentation also contained a comparison of the analysis of alternatives process under REACH and biocides, indicating the similarities and differences.

There was general appreciation for the presentations and the information and feedback provided. The following comments for further reflection were provided:

- A general request for template and guidance, with the possible re-use of REACH guidance available, and a suggestion to provide a decision tree to go through different scenarios.
- The applicability of this exercise for the first approval instead of renewal was questioned, especially for active substances being a potential candidate for substitution but not meeting the exclusion criteria.
- The possible improvement of the information needed. How to involve the applicant to provide information on alternatives, especially for substances which are potential candidates for substitution but are not meeting the exclusion criteria since for those substances the applicant has no incentive to provide information on alternatives. To improve the ECHA data-base, for example the search functionality. Some considerations of the public consultation were proposed: i) better timing; ii) disclose if possible more information on the uses; iii) possibility to contact parties who submitted information and a more direct dialogue with stakeholders to obtain more accurate and target information, such as the needs in the market or possibilities for substitution from manufacturers or downstream users.
- The members were asked on possible issues faced causing their usually low contribution to the public consultation. Lack of expertise referring specifically to the limited capacity to evaluate the technical and economic feasibility of alternatives as well as non-chemical alternatives were mentioned. The members indicated their potential needs to consult outside their organisation and wondered if it would not be more efficient to centralise the possible investment in expertise and knowledge.

To better understand the situation, a questionnaire was sent out to the members after the BPC meeting to gather input, suggestions, and problems encountered (resources as well as expertise).

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 38th meeting of BPC

2-5 March 2021

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-37	
The revised version of the minutes of BPC-37 was agreed.	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website.
Item 5 – Administrative issues	
-	**SECR**: to upload the presentation on the reorganisation of the activities within ECHA on CIRCABAC IG
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 **12 March 2021.**
Item 6.2 - Outlook BPC 2014 - 2020	
The BPC took note of the document.	-

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 Instruction manual on preparing a BPC opinion on active substance approval and renewal in case of a full evaluation and corresponding opinion templates	
The BPC discussed and agreed on the documents.	**SECR**: to publish the documents on the BPC CIRCABC IG and the ECHA website.
7.2 Draft BPC opinion silver zinc zeolite for PT 4	
The BPC adopted by consensus 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 **16 April 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 **23 March 2021** and publish it on the ECHA website.
7.3 Draft BPC opinion on silver zeolite for PT 4	
The BPC adopted by consensus 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 **16 April 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 **23 March 2021** and publish it on the ECHA website.
7.4 Draft BPC opinion on silver copper zeolite for PT 4	
The BPC adopted by consensus 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 **16 April 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 **23 March 2021** and publish it on the ECHA website.

7.5 Draft BPC opinion on silver sodium hydrogen zirconium phosphate for PT 4	
The BPC adopted by consensus 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 **16 April 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 **23 March 2021** and publish it on the ECHA website.
7.6 Revised Assessment Report following the submission of data after active substance approval:	
7.6.1. PBO 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.	**-**
7.6.2. Ampholyt for PT 2, 3 and 4	
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 **16 April 2021.**
7.6.3 Bardap 26 for PT 8	
The member from IT informed the BPC about the evaluation of the data submitted after the approval. The evaluation was agreed upon.	**Member (IT):** to forward the revised assessment report with the List of Endpoints to the SECR by **16 April 2021.**
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 Instruction manual on preparing a BPC opinion on an Union authorisation application including the opinion template	
The BPC discussed and agreed on the documents.	**SECR**: to publish the documents on the BPC CIRCABC IG and the ECHA website.
8.3 Draft BPC opinion on an Union authorisation application for a biocidal product family containing peracetic acid	
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 **19 March 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, draft SPC and final PAR to COM by **23 March 2021** and publish them on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **16 April 2021**.
Item 9 –Any other business	
9.1 Dedicated session on analysis of alternatives	
-	-

oOo

Part III - List of Attendees

Members
BALDASSARRI Lucilla (IT)
BORGES Teresa (PT)
BROVKINA Julija (LV)
BUEHLER Dominique (CH)
CARBERRY Stephen (IE)
CEBASEK Petra (SI)
CHEZEAU Aurelie (FR)
GONZALEZ MARQUEZ Maria Luisa (ES)
GREGERSEN Nina Falk (DK)
HADJIGEORGIOU Andreas (CY)
HAHLBECK Edda (SE)
HAKAITE Palmira (LT)
JAGER Stefanie (DE)
JARRETY Helene (BE)
KOIVISTO Sanna (FI)
LANS Martine (NL)
MERISTE Anu (EE)
MIKOLAS Jan (CZ)
MIKOLASKOVA Denisa (SK)
RANDALL Marit (NO)
RZODECKO Helena (PL)
SZENTGYORGYI Timea (HU)
VAGIAS Vasileios (EL)
VRHOVAC FILIPOVIC Ivana (HR)
Alternate members
ENSCH Svenja (LU)
MALLIA Lothar Paul (MT)
PUERGY Reinhild (AT)
Advisers
CATALDI Lucilla (IT)
COLLET Romy (FR)
EHNI Markus (DE)
FRANK Ulrike (SE)
GKILPATHI Dimitra (EL)
HAMALAINEN Anna-Maija (FI)
HUSZAL Sylwester (PL)
IAKOVIDOU Mary (SE)
IZQUIERDO MOYA Inmaculada (ES)
KALKERS Lucas (NL)
KANDRIS Ioannis (EL)
KRAFTE Kristine (LV)
LEPAGE Anne (BE)
O'BEIRNE Tara (IE)
PAXINOU Chara (EL)
RUIZ LÓPEZ Elena Fuensanta (ES)
SCHMALHOLZ Ellen (SE)
SCHOEP Piet (NL)
TUUSA Tiina (FI)
VISSER Alette (NL)
WEINHEIMER Viola (DE)
European Commission
CHATELIN Ludovic (DG SANTE)
DELVAUX Vincent (DG SANTE)
GKINIS Georgios (DG SANTE)
NAGTZAAM Martinus (DG SANTE)
Accredited Stakeholder Observers
CINGOTTI Natacha
COGGINS Christopher
GARMENDIA Irantzu
LEROY Didier
MIHAI Camelia
QUAGLIA Giancarlo
RITO Elias

VAN BERLO Boris	VAN DE PLASSCHE Erik
ASO experts for AP 09.01	VAN GALEN Joost
COR Gabrielle	
FREEMANTLE Mike	**Apologies**
GENERO Elena	RO
GREY Adrian	
VAN VELTHOVEN Martijn	
Applicants	
EU Silver Task Force	
Endura S.p.A.	
Evonik Operations GmbH	
Lonza Cologne GmbH	
SOPURA	
ECHA Staff	
CARLON Claudio	
GLANS Lotta	
HONKA ANNI	
KENIGSWALD Hugues	
KREBS Bernhard	
KURONEN Terhi	
KVATCHADZE Giorgi	
MOTTET Denis	
MULLER Gesine	
PAPADAKI Paschalina	
RUGGERI Laura	
SAEZ RIBAS Monica	
STASKO Jolanta	

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-38

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-38 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2	BPC-A-38-2021_rev1	Draft agenda	
4	BPC-M-37-2020	Draft minutes from BPC-37	
5.1	-	Administrative issues and report from the other Committees	
6.1	BPC-38-2021-01 BPC-38-2021-02 BPC-38-2021-03 BPC-38-2021-04	BPC Work Programme for active substance approval, Union authorisation, ED assessment and outlook for BPC	
6.2	BPC-38-2021-05	Outlook BPC 2014 - 2020	
7.1	BPC-38-2021-06	7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval	
	BPC-38-2021-07	7.1.2. Working procedure for active substance approval	
	BPC-38-2021-08		
	BPC-38-2021-18		
7.6	BPC-38-2021-06	7.6.1. PBO for PT 18	
	BPC-38-2021-07	7.6.2. Ampholyt for PT 2, 3 and 4	
	BPC-38-2021-08	7.6.3. Bardap 26 for PT 8	
8.1	-	Update on Union authorisation	
8.2	BPC-38-2021-16	Instruction manual on preparing a BPC opinion on an Union authorisation application including the opinion template	
9.1	-	Dedicated session on analysis of alternatives	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.4	BPC-38-2021-09A	silver zinc zeolite PT 4	Draft BPC opinion

	BPC-38-2021-09C		Open issues
	BPC-38-2021-09D		SECR explanatory note on silver compounds PT4 for BPC-38
7.3	BPC-38-2021-09E		ECHA-EFSA Silver compounds biocides_FCM February 2021
	BPC-38-2021-09F		Letter from Applicant to BPC Chair “Comments applicant”
	BPC-38-2021-19_Room doc 1		Room document
7.4	BPC-38-2021-10A	silver zeolite PT 4	Draft BPC opinion
	BPC-38-2021-09C		Open issues
	BPC-38-2021-11A	silver copper zeolite PT 4	Draft BPC opinion
7.5	BPC-38-2021-09C		Open issues
	BPC-38-2021-12A	silver sodium hydrogen zirconium phosphate PT 4	Draft BPC opinion
	BPC-38-2021-09C		Open issues
8.3	BPC-38-2021-17A	UA: product family containing peracetic acid	Draft BPC opinion
	BPC-38-2021-17B		SPC
	BPC-38-2021-17C		PAR
	BPC-38-2021-17C1		Conf Annex to PAR
	BPC-38-2021-17D		Open issues
	BPC-38-2021-20_Room doc 2		Room document
	BPC-38-2021-21_Room doc 3		Room document

18 February 2021
BPC-A-38-2021_rev1

Draft agenda

38th meeting of the Biocidal Products Committee (BPC)

2 – 5 March 2021

Meeting is held virtually via WebEx

Starts on 2 March at 10:30, ends on 5 March at 13:00

The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-38-2021

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-37

BPC-M-37-2020

For agreement

5. – Administrative issues

5.1. Administrative issues

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-38-2021-01; BPC-38-2021-02; BPC-38-2021-03; BPC-38-2021-04

For information

6.2. Outlook BPC 2014 - 2020

BPC-38-2021-05

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-38-2021-06

For information

7.1.2. Instruction manual on preparing a BPC opinion on active substance approval and renewal in case of a full evaluation and corresponding opinion templates

BPC-38-2021-07, BPC-38-2021-08, BPC-38-2021-18

For agreement

7.2. Draft BPC opinion on silver zinc zeolite for PT 4

Previous discussions: TM-II-2013, TM-IV-2013, WG-III-2015, WG-III-2016,WG-V-2016, WG-V-2017, BPC-27

BPC-38-2021-09A, C

For adoption

7.3. Draft BPC opinion on silver zeolite for PT 4

Previous discussions: WG-V-2017, BPC-27

BPC-38-2021-10A, C

For adoption

7.4. Draft BPC opinion on silver copper zeolite for PT 4

Previous discussions: WG-V-2017, BPC-27

BPC-38-2021-11A, C

For adoption

7.5. Draft BPC opinion on silver sodium hydrogen zirconium phosphate for PT 4

Previous discussions: WG-V-2017, BPC-27

BPC-38-2021-12A, 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).

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

7.6.1. PBO for PT 18

BPC-38-2021-13
For agreement

7.6.2. Ampholyt for PT 2, 3 and 4

BPC-38-2021-14
For agreement

7.6.3. Bardap 26 for PT 8

BPC-38-2021-15
For agreement

8. – Union authorisation**

8.1 Update on Union authorisation

For information

8.2 Instruction manual on preparing a BPC opinion on an Union authorisation application including the opinion template

BPC-38-2021-16
For agreement

8.3 Draft BPC opinion on an Union authorisation application for a biocidal product family containing peracetic acid

Previous discussion: WG-III-2020

BPC-38-2021-17A, B, C, D
For adoption

9. - Any other business

9.1 Dedicated session on analysis of alternatives

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

38th meeting of the Biocidal Products Committee (BPC)

Virtual meeting via WebEx

2 March 2021: starts at 10:30; 5 March 2021 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 2 March: (starts at 10:30, ends at 18:00)

Items 1-5	Opening items and administrative issues
Item 6	Work programme for BPC
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. Instruction manual on preparing a BPC opinion on active substance approval and renewal in case of a full evaluation and corresponding opinion templates
Items 7.2-7.5	Draft BPC opinions on silver zinc zeolite, silver zeolite, silver copper zeolite and silver sodium hydrogen zirconium phosphate for PT 4

Wednesday 3 March: (starts at 10:30, ends at 17:00)

Items 7.2-7.5	(cont'd)
Item 7.6	Revised Assessment Report following the submission of data after active substance approval:
	7.6.1. PBO for PT 18
	7.6.2. Ampholyt for PT 2, 3 and 4
	7.6.3. Bardap 26 for PT 8

Thursday 4 March: (starts at 10:30, ends at 17:00)

Item 8.1	Update on Union authorisation
Item 8.2	Instruction manual on preparing a BPC opinion on an Union authorisation application including the opinion template
Item 8.3	Draft BPC opinion on an Union authorisation application for a biocidal product family containing peracetic acid
Item 10	Action points and conclusions

Friday 5 March: (starts at 10:00, ends at 13:00)

Item 9.1	Dedicated session on analysis of alternatives

End of meeting

o0o