14 December 2022

BPC-M-44-2022_FINAL

Final non-confidential minutes of the 44th meeting of the Biocidal Products Committee (BPC)

26-29 September 2022

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chair of the Biocidal Products Committee (BPC) welcomed the participants to the 44th BPC meeting which took place as a virtual meeting via Webex.

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

32 Advisers (of whom 3 in double role also as an alternate member) and 10 representatives from an accredited stakeholder organisation (ASO) were present at the meeting. Five representatives from the European Commission attended the meeting and two EFSA observers.

Applicants were invited and present for their specific substances under agenda item 7, biocidal products under agenda item 8 and Article 15(2) item under agenda point 10 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-44-2022_rev2) 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 Interact/Website as part of the meeting minutes.

The Chair informed the meeting participants that the meeting is 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-43

The revised draft minutes from BPC-43 (BPC-M-43-2022), incorporating the comments received, were agreed.

The Chair mentioned that all actions from the previous BPC-43 meeting were carried out.

Actions:

- **SECR:** to upload the agreed minutes from BPC-43 to the BPC Interact and to the ECHA website after the meeting.

5. Administrative issues

5.1 Administrative issues

The Chair informed the meeting that the intention is to organise the 22-24 November meeting as a face-to-face meeting.

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 2022 the planned opinions are listed in the “Outlook” document.

The total number of expected adopted opinions for 2022 will be 57. For Union authorisation applications (UA) there is a substantial increase compared to 2021: from 15 to 22. For the active substance approval process (AS) there is a slight decrease in the number of adopted opinions compared to 2021: from 18 to 17 (total) and 14 to 12 (Review Programme). Compared to the information presented at the last meeting: zineb (Article 15(2) mandate) will not be discussed at the next BPC while the intention is to discuss the two PT 18 evaluations for Chrysanthemum cinerariaefolium extracts at the next BPC.

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 especially be made on backlog reports submitted before 1 September 2013 for which decisions must still be based under BPD principles, which is becoming more and more problematic. The Commission also asked to the concerned Member States why a third of the dossiers originally planned to be discussed in the BPC in 2022 are finally dropped from the planning, and invited Member States to better respect the announced planning in order to make progress in the review programme.

The Chair asked the evaluating Competent Authorities being rapporteur for active substances or Union authorisations scheduled for discussion at the fourth BPC meeting of 2022 (BPC-45) to confirm their planning to the SECR as soon as possible.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by **13 October 2022**.

6.2 Update on active substance approval and Union authorisation

An update on Union authorisation (UA) and Active substance approval (AS) was given by the SECR:

i) Workload on AS and UA

SECR presented the current workload of AS and UA dossiers in peer review and the forecast for the end of 2022.

ii) Update from AS and UA processes

The SECR reminded the members to update the planning document provided via the Interact Collaboration tool if there are changes in their planning of submissions. In addition, the SECR informed about the ongoing bilateral meetings with the management of several Member State CAs, the development of a new procedure for new data on an active substance submitted during the product authorisation phase, and about the upcoming publication of a list of Member States allowing creosote-treated articles on their market. A request was made to provide the timelines for upcoming process flows as soon as possible. The SECR also reminded about the publication of the revised Working Procedure for Union authorisation applications, the revised procedure for the linguistic review of translations of the SPC for UA as well as the ECHA opinions available on the ECHA website (https://echa.europa.eu/opinions-on-union-authorisation) following an application for classification of a change. The SECR also noted that recently very poor quality of the SPC translations were submitted.

The SECR informed the BPC that the CG agreed on the approach concerning long-term storage stability studies. This approach will be applied for UA applications too. The BPC members were invited to contact their CG colleagues for more details.

iii) Survey on Interact and SBP linguistic procedure

SECR informed that following the survey on the Interact tool for commenting the template for the RCOM has been updated in accordance with the comments received. SECR is working on a planning for the amendments of the Interact tool itself. A full update on the actions following the survey will be presented in BPC-45. SECR informed also that work is ongoing on the revision of the procedure of the linguistic review of SPCs for UA same biocidal products. SECR will present a new proposal in one of the upcoming BPC meetings.

Actions:

- **SECR**: to upload the presentation to Interact.

6.3 Proposal revision of working procedures for active substance approval and Union authorisation with respect to providing information during peer review

A proposal on the revision of the working procedures for active substance approval and Union authorisation with respect to providing information during peer review was given by the FI member. The background of the proposal is that it is relevant only that the information is provided within 10 working days after the respective Working Group, and no longer that only the information already available at the date of the Working Group may be submitted. The proposal was accepted by the meeting. Consequently, the SECR will revise the relevant BPC documents.

Actions:

- **SECR**: to upload the document to Interact/BPC CIRCABC IG.

7. Applications for approval of active substances

7.1 Validation of the PBT/vPvB or ED status of an active substance by the BPC with respect to the assessment whether the exclusion or substitution criteria are met

The Chair introduced the topic on validation of the PBT/vPvB or ED status of an active substance by the BPC with respect to the assessment whether the exclusion or substitution criteria are met. The document was agreed with the provision that the document will be aligned with the connected CA document. One member will provide some minor – more editorial – comments in writing.

Actions:

- **SECR**: to upload the document to Interact/BPC CIRCABC IG.

7.2 Draft BPC opinion on Ozone generated from oxygen for PT 02, 04, 05 and 11

The Chair welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case. The Chair stated that an opinion for ozone generated from oxygen for the same PTs was already adopted and published following an application to Germany (ECHA/BPC/303/2021 – ECHA/BPC/306/2021). The Chair also clarified that a harmonised classification and labelling proposal for ozone is scheduled to be discussed in the Risk Assessment Committee: all endpoints except carcinogenicity are scheduled for RAC 63 and the carcinogenicity endpoint is scheduled for RAC-64.

As first point of discussion was the applicability of the Article 19(4) to the biocidal products of Ozone generated from oxygen, as agreed in the recent CA document. (CA-June22-Doc.4.7). This document indicates that: "*If the in situ biocidal product of an IGS fulfils any of the criteria listed in Article 19(4), the in situ biocidal product should not be authorised for the use by the general public.*"

Some members and the applicant expressed the opinion that to decide whether biocidal products of ozone generated from oxygen can be authorised for the use by general public can only be taken at the product authorisation stage as it depends on the classification of the biocidal product. It was noted that the harmonised classification for "pure" ozone is applied in the active substance assessment, while in product authorisation the classification of the biocidal product needs to be considered. COM clarified that the intention of the CA document was to agree that both the biocidal products falling under first and second indent of the relevant guidance on active substances generated in-situ are included in the scope of Article 19(4). In that document however, an example was taken where the reference product referred as being constituted of 100% of the "pure" active substance. For ozone generated from oxygen it was indicated that there may be uses by the general public applied for under product authorisation where this is not the case and use by the general public may be authorised. Subsequently, it was agreed that the condition "products shall not be authorised for use by the general public" as presented in the draft opinion, will not be proposed as an approval condition in the opinions.

The Chair introduced the combined List of Endpoints (LoEP) for ozone generated from oxygen. This combined LoEP was prepared by the SECR being a combination of the LoEPs from the applications to Germany and the Netherlands. It was agreed that a combined LoEP is essential for the biocidal product authorisation stage. It was agreed that the SECR will in consultation with DE and NL finalise the combined LoEP and will inform the BPC and applicants (if needed) at the next BPC meeting. It was agreed to publish the combined LoEP as an annex to the Assessment Reports of both applications.

It was discussed whether there are differences in the assessment between both applications. Here it was concluded that this may be the case for the risk assessment for PT 11. The BPC recommended that this needs to be addressed at product authorisation stage.

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The opinions for PT 2, PT 4, PT 5 and PT 11 were adopted by consensus.

COM explained that a combined decision will be taken based on both applications. COM further explained that in order to prepare the implementing regulation, a precautionary approach will be used when combining the opinions per PT.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **21 November 2022**.
- **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 **21 October 2022** and publish it on the ECHA website.
- **SECR:** to amend the combined LoEP and consult with the members from DE and NL.

7.3 Draft BPC opinion on Mecetronium ethyl sulphate (MES) for PT 01

The Chair welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case. In the introduction, the complex history of the case was highlighted explaining that the ECHA accordance check had failed twice in 2020 and 2021 respectively, due to the identified data gaps in the analytical information. The case entered the peer review phase in January 2022 with a proposal for non-approval due to the lack of sufficient analytical information. In May 2022, at the Working Group (WG) stage, however, the applicant submitted the missing information and the reference specification was agreed by the APCP WG in an ad hoc follow-up discussion. Furthermore, five relevant impurities were identified in the assessment by the eCA. While acceptable risks were concluded in the human health and environmental risk assessment, the ED assessment was found as insufficient both by the Human Health (HH) and the Environment (ENV) WG. In addition, the ENV WG concluded that further information is required for concluding on the bioaccumulation (B) criteria in the PBT assessment.

In the draft BPC opinion a non-approval proposal was maintained, however based on reasons different from the initial non-approval proposal in the assessment submitted for peer review, due to the changes at the WG and in the WG follow-up stage.

The main argumentation for the non-approval in the draft opinion was related to the relevant impurity diethylsulphate (DES) which raises a specific concern due to its harmonised classification as Carc. 1B, Muta. 1B. Furthermore, DES is included in the List of Substances Prohibited in Cosmetic Products (Regulation (EC) No 1223/2009), whereas referring to BPR Art 19(9), a biocidal product intended for direct application to the skin shall not contain any non-active substance that may not be included in a cosmetic product. COM stated that from a legal perspective the Article 19(9) based argumentation is not applicable in this case, as it has been clarified in previous discussions in the CA meeting that impurities are part of the active substance, while Article 19(9) of the BPR refers to non-active substances or co-formulants present in the biocidal product. In turn, COM rather questioned if from a risk assessment perspective the impurity would lead to an unacceptable risk. It was explained that no risk assessment was performed for this impurity and the related draft argumentation for the non-approval was only hazard-based from Article 19(9). In this connection, the lack of a carcinogenicity study was raised and it was clarified that also for the active substance only a semi-quantitative risk assessment was conducted due to the fact that the most critical effects identified in toxicological studies were local effects. Furthermore, in line with Article 17 of Regulation (EC) No 1223/2009 unintended trace impurities of Annex II substances stemming from the manufacturing process are permitted - which however is of no relevance in the context of the BPR. Based on the arguments presented above, it was concluded by the BPC that the reference to the BPR Article 19(9) should be removed as an argumentation for the non-approval proposal. In addition to this, the applicant referred to practical experience where DES is already present in cosmetic products, and mentioned comparable biocide active substance cases where concerns have not been raised with regard to the cosmetics regulation. The applicant further drew attention to the low LOQ/LOD applied in the quality control as well as to the unstability of the impurity due to its physico-chemical properties. Furthermore, it was noted that the impurity will not have an impact on the classification of the active substance at the maximum content set in the reference specification.

As another argument for the non-approval proposal, the identified data gaps on the ED assessment and B assessment were discussed. Contrary to the suggested assessment submitted for peer review (where MES was identified as not meeting the ED criteria), the HH WG and ENV WG had concluded that the ED assessment was not sufficient and it was not possible to conclude on the ED properties of MES. The HH WG had asked for a more substantiated read-across justification while the ENV WG had concluded that further test data are required since extension of the applied weight of evidence approach was not considered to be sufficient. The ENV WG had further decided that additional data was necessary to conclude on the B assessment. During the peer review stage, the applicant provided additional information from public literature with the aim to complete the data package on the human health ED assessment and B assessment. Following a discussion on the use of published information in the assessment of active substances, the BPC did not take a position regarding this question.

With regards to the ED assessment, it was acknowledged that the tiered approach followed in the approval process complicates the processing of active substances. In the case of MES, during the peer review and at the WG stage it was unclear whether the data gaps related to analytical information could be resolved. Thereby in the case of data gaps on other data than ED which would be already leading to a non-approval proposal, no conclusion on the ED assessment would be required. The applicant claimed that from procedurally they were not given the opportunity to provide additional information since the ED conclusion was changed only at the WG stage. The applicant was however aware

of potential data gaps already before the start of the peer review and expressed willingness to finalise the read-across argumentation.

Besides the non-approval argumentation related to the relevant impurity and identified data gaps, a discussion took place on the coverage of the reference specification by the toxicological and ecotoxicological test batches. The rapporteur explained that since the performance of the toxicological and ecotoxicological studies for the dossier submission in 2007, there has been no change in the manufacturing process of the active substance. Furthermore, the production takes place in a single location under GMP conditions and quality control data was available to monitor the level of certain impurities. On the contrary, the five batch analysis used for the setting of the reference specification was performed in 2021-2022. Due to the different analytical methods, a direct comparison of the reference specification and the test batch impurity profiles was not possible. However, some compounds have been monitored continuously and considering that there is no change in the manufacturing process, it was possible to conclude that the reference specification is covered by the test batches. The assessment of the test batches was commented in the HH and ENV WG ad hoc follow-ups and the revised assessment was presented in the updated CAR. Two members expressed their support to the conclusions by the eCA. A detailed explanation of the issue following the conclusion by the eCA will be included in the assessment report while reference to this issue in the opinion will be removed since it was agreed not to be a reason for a non-approval. One member disagreed since they had a major concern on the conclusions in the assessment report and claimed that it is not possible to demonstrate the interlink between the reference specification and the test material based on the available information. This member indicated that these concerns were expressed during the HH WG ad hoc follow-up consultation. During that consultation no conclusion was reached with respect to these concerns. Rather, the eCA was asked to revise the evaluation based on all comments made. The BPC agreed with this revision by the eCA. However, the concerns expressed by the member remained. Following the exchange on the above aspects, the non-approval proposal based on the presence of DES as relevant impurity and on the data gaps on the ED and B assessment were discussed. One member stated that they cannot support the proposed conclusion of the draft opinion since Article 19(9) was considered not applicable, and the ED assessment part is not clear. In addition they reiterated the problem with the validation of the reference specification by the test batches. A number of BPC members were reluctant to include the DES relevant impurity as reason for the non-approval proposal. However, although Article 19(9) is not applicable, it was agreed that there is a toxicological concern related to this impurity in any case. Therefore, it was agreed that in the opinion and in the assessment report the concerns and the justification for not performing a risk assessment for this impurity should be clearly described. On the other hand, a number of BPC members expressed their support to base the non-approval on the identified data gaps in the ED assessment and B assessment. A clear conclusion both on the HH and ENV ED assessment related to the exclusion and substitution criteria is needed for the approval of an active substance and in the case of MES this is not possible due to insufficient information. In conclusion, the identified data gaps in the ED assessment and B assessment were agreed to justify a proposal for non-approval. In contrast, the presence of DES was seen as an element of concern but not as an argumentation for non-approval. A member disagreed with the final argumentation to base the non approval proposed for the active substance. According to this member, not only the data gap in the ED assessment but also the concern related to the coverage of the (eco)tox batches by the reference specifications should be considered as reasons to justify the non approval proposal.

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table.

The opinion was adopted by majority.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **21 November 2022**.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **Member minority (CZ):** to submit the minority position by **6 October 2022**.
- **SECR:** to forward the adopted opinion to COM by **21 October 2022** and publish it on the ECHA website.

7.4 Draft BPC opinion on Sulfur dioxide generated from sulfur by combustion for PT 04

The Chair welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The rapporteur Germany introduced the case.

Sulfur dioxide is used by professionals in wooden wine barrels by placing a sulfur tablet in the barrel which releases sulfur dioxide after ignition.

Sulfur dioxide is widely used as a food additive: it is regulated under Regulation (EC) No. 606/2009[1], under Regulation (EC) No. 607/2009[2] and as well sulfur dioxide is authorised under Regulation EC 1333/2008[3] as a food additive. In 2016, it has been re-evaluated by EFSA[4] as a food additive. The Chair informed that in parallel to the evaluation under the BPR of sulfur dioxide EFSA has undertaken a follow-up to its re-evaluation opinion of sulfur dioxide-sulfites to address the data gaps previously identified and the recommendations issued at the time of the 2016 re-evaluation. Subsequently, EFSA participated in the discussions of the Human Health Working Group of sulfur dioxide generated from sulfur by combustion in order to discuss potential divergences of opinions between the respective evaluations of sulfur dioxide. However, it was noted by the Chair that EFSA does not have a formal role in the assessment performed under the BPR. The text in the opinion on the re-evaluation process by EFSA was agreed.

Following several questions from the members and applicant the process followed - including the discussions which took place in the Human Health Working Group - were clarified. The Chair informed that after the EFSA opinion is adopted an analysis will be

[1] COMMISSION REGULATION (EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions.

[2] COMMISSION REGULATION (EC) No 607/2009 of 14 July 2009 laying down certain detailed rules for the implementation of Council Regulation (EC) No 479/2008 as regards protected designations of origin and geographical indications, traditional terms, labelling and presentation of certain wine sector products.

[3] REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives.

[4] Scientific Opinion on the re-evaluation of sulfur dioxide (E 220), sodium sulfite (E 221), sodium bisulfite (E 222), sodium metabisulfite (E 223), potassium metabisulfite (E 224), calcium sulfite (E 226), calcium bisulfite (E 227) and potassium bisulfite (E 228) as food additives (http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4438/pdf).

made by both Agencies if there are discrepancies between both opinions and assessments. If this is the case, a joint note will be prepared and published.

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **21 November 2022**.
- **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 **21 October 2022** and publish it on the ECHA website.

7.5 Draft BPC opinion on Sulfur dioxide released from sodium metabisulfite for PT 09

The Chair welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The rapporteur introduced the case. Sulfur dioxide generated from sulfur by combustion in PT 4 and this evaluation were always discussed together in the Working Groups.

As it is a sulfur dioxide releasing substance, the RAC opinion and classification of sulfur dioxide as mentioned in PT4 sulfur dioxide generated from sulfur by combustion applies. Neither the active substance nor the releaser fulfils the exclusion or substitution criteria. The use evaluated is a sticker containing the releaser sodium metabisulfite. This ready-to-use product is applied to shoe boxes by professional users prior to long transport of leather shoes to protect the shoes from mold.

Reference was made to the discussions following agenda item 7.4 including the reference to the EFSA re-evaluation in the opinion and in the assessment report.

It was clarified that the releaser will be mentioned in the opinion with the EC and CAS number.

All other items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **21 November 2022**.
- **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 **21 October 2022** and publish it on the ECHA website.

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8. Union authorisation

8.1 The applicant's involvement during the opinion forming process

The SECR presented a revised proposal in relation to the applicant`s involvement during the opinion forming process. A proposal was made with the aim to simplify the process in order to cope with the high number of Union authorisation applications entering the opinion forming process. Two revised scenarios were proposed for the BPC members consideration. The BPC members supported Scenario 1. This scenario entails that the eCA provides a document used for the 30 days commenting period (as laid down in Article 44(1) of the BPR) during the evaluation step that includes comments from the applicant and the responses from the eCA to those comments. After this 30 days commenting period the applicant will be only actively involved during the Working Group, meaning that the applicant will not be given a second opportunity to provide comments before the Working Group meeting.

The working procedures for Union authorisation and active substance approval will be revised in accordance with the agreement for BPC-45. In addition, the SECR will prepare a template to be used for the 30 days commenting period by the applicant before the eCA submits the assessment for peer review to ECHA. The new approach is planned to be applied for process flow 48 (UA) and 49 (AS).

8.2 Guiding principles on handling information provided by the applicant during UA process

ECHA introduced the document. It was explained that the trigger for the document was that applicants often are unaware about when they are allowed to provide information during the UA process. Also evaluating Competent Authorities sometimes have acted differently when extra information was provided later in the process. The document therefore aims to provide clarity on when information can be provided and on whose initiative. A further aim is to come to a harmonised approach towards the applicants, which should result in transparent and equal treatment in all cases.

Following the introduction seven members took the floor and expressed their general support for the document but they also flagged some issues:

- Member States have very different interpretations of what should be checked in a validation;
- It is currently not feasible to restrict the providing of additional data in the validation and evaluation phase to only one possibility, due to the quality of the dossiers as submitted by the applicants;
- There is unclarity about the situations in which the 90 days and 180 days deadline for providing information may be extended;
- Information is requested in multiple messages which sometimes has to do with the nature of the evaluation. In such cases APCP and EFF are often requested first and HH and ENV in a second round. Sometimes there is an organisational background.

- Some members supported the message templates, several other indicated that they already have their own templates in place. A list with items that should at least be in these messages was supported.

The ASOs representing industry were critical about the document and would like to have flexibility in the number of requests for additional information. It was pointed out that new guidance may become available during the lengthy procedures which may require the generation of new information. Informing the applicants about a final document would be important and the ASOs indicated that they do not reach all applicants when forwarding such information.

Finally COM reminded that it is the responsibility of the applicants to provide a complete dossier of sufficient quality in the first place and at the moment of its submission, and not wait requests for data from the eCAs. An effort to harmonise the way of working by all involved actors will be necessary to improve the current processes.

The SECR will prepare a revised version for the next meeting for agreement.

8.3 Draft BPC opinion on an Union authorisation application for a biocidal product family containing hydrogen peroxide for PT 2, 3, 4

The Chair welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case and reminded that the APCP WG II 2022 had found the metal corrosion tests included in the PAR as not reliable, which led to a data gap for this endpoint. The rapporteur explained that, following the APCP Working Group, the applicant had provided new metal corrosion test data, which the eCA had found acceptable. Thus, the rapporteur proposed the new test data to be included in the data package for this Union authorisation application, although this data had not been requested by the APCP Working Group. The PAR and the IUCLID dossier had already been updated accordingly and the new test report had been circulated to the BPC members prior to the BPC meeting.

A brief discussion took place related to this point. It was noted that the APCP Working Group could not have requested the new data as it was not readily available to the applicant. Thus, the conclusions of the APCP Working Group were in line with the procedure in place at the time. It was further noted that amendments to this procedure were endorsed by the BPC members during BPC-44 (Item 6.3). Considering these new amendments and the fact that the new data were provided to the eCA within 10 working days after the discussion at the APCP Working Group, the BPC agreed that the introduction of these new data can be accepted for this specific Union authorisation.

All other items in the open issue table were addressed and conclusions reached were recorded in the open issue table. The opinion was adopted by consensus. One BPC member abstained from the vote for the purpose of consistency with previous abstentions from this BPC member and because the approach followed in this case for the introduction of new data during opinion forming was deviating from the currently published procedure.

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 **14 October 2022.**

- **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, minority posision, draft SPC and final PAR to COM by **21 October 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **6 December 2022**.

8.4 Draft BPC opinion on an Union authorisation application for a biocidal product family containing peracetic acid for PT 3, 4

The Chair welcomed the applicant for this item. The ASOs were not allowed to be present during the discussion. The rapporteur briefly introduced the case. All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The 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 **14 October 2022.**
- **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, minority position, draft SPC and final PAR to COM by **21 October 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **6 December 2022**.

8.5 Draft BPC opinion on an Union authorisation application for a biocidal product family containing active chlorine released from sodium hypochlorite for PT 2, 3, 4, 5

The Chair welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case.

Two open issues concerned the missing use instructions and an Excel sheet for generating relevant dilutions of the products provided by the applicant. It was noted by ECHA that for most of the meta-SPCs under point 5.1 and/or 6 in the SPC the following phrase has been included: "*The applicant should give indications of application of the product (dilution, quantity applied on surfaces, etc.) on the label in order to guarantee a proper application of the product. The volume of product to be diluted and the specified volume of water should be clearly indicated on the label (e.g. take 10 mL of product and dilute in 1 L water)*". It was further noted that such phrase is irrelevant for the SPC recipient (i.e. professional or non-professional user), as it concerns the product manufacturer and the individual product labelling. During the discussion it was clarified that the SPC must include information on application doses and instructions for use as indicated in Article 22(2)(l). Such approach may also be problematic from an enforcement perspective and for the possible future SBP applications. COM noted that without proper use instructions, the SPC is not in line with the legally recognised format, as the formula is insufficient to satisfy the

legal requirements. The rapporteur stated that an Excel sheet with a formula for generation of product dilutions has been provided by the applicant and will be made available in an annex to the public PAR. COM indicated that a separate document with relevant information for use would be problematic as all relevant information should be included in the act and its SCP Annex. The rapporteur informed that a similar approach was followed in previous UA and NA applications. According to the rapporteur, accounting for the size and complexity of the families, it would be very difficult to include this information in the SPC, as there are many products and doses for different conditions (clean/dirty, temperature, contact time) and target organisms. It was also clarified that the formula is relatively straightforward as only the dilution of the concentrated products is missing as the application rates of the active substance are included in the SPC. The members agreed to continue with the approach followed by the rapporteur; the previous similar UA and NA cases will be checked by ECHA and BPC members should inform if there are concerns with enforcement. The concrete implementation of the approach will be further discussed with the rapporteur taking into account the previous cases cited.

The applicant commented the non-authorisation proposal of several products due to lacking corrosion to metals studies. The applicant proposed a default classification instead of providing data. The rapporteur informed that default classification cannot be used as it could lead to “over classification”. The rapporteur instead had requested the data during the evaluation and informed the applicant about the possible consequences of not providing the data. This issue was discussed at the APCP WG once in an early WG discussion held in 2019 and during APCP WG-II-2022.

A member informed that they do not agree with the approach to double the efficacious doses in order to compensate the degradation of 50% of the active substance, for some of meta-SPCs. According to this member overdosing is not acceptable and there is no valid reason to allow an overdosing when the efficacy of lower concentrated solutions is demonstrated.

Lack of efficacy data on aged products results into very short shelf lives for the majority of the meta-SPCs. The applicant informed that they tried to submit efficacy data on aged products as soon as they became aware that such tests are required. However, the APCP WG did not request the data. Yet, this data was submitted for the ad hoc follow up of the EFF WG. It was clarified by the rapporteur and by the Chair of the EFF WG that data were only asked to address the impact of alkaline co-formulants on the minimum level of efficacy of both product families. The fact that the data were provided on aged samples is not relevant as the EFF WG did not request such data to fill the data gap on the efficacy of aged product.

A member submitted a position paper on storage temperature of sodium hypochlorite based products. The objective of this paper was to require that for all active chlorine based products, that are to be authorised with storage stability data obtained from tests conducted at 20 °C, the storage temperature has to be set to ≤ 20°C. This is needed in order to minimise the degradation of the active substance and the formation of chlorate with increased temperature during product storage. This approach was followed in this application. It was questioned by the applicant whether requirement to store the products under 20 °C is feasible and enforceable. It was concluded by the Chair that further consultation by the APCP WG is required.

A member questioned the approach taken to include more than one formulation type within one meta-SPC. However, as according to the new BPF concept (“Implementing the new

concept of biocidal product families", CA-Nov14-Doc.5.8 – Final.rev3) concentrates and RTU products can be allocated in one meta-SPC, it was agreed that the meta-SPC's do not need to be split.

A member commented the agreement made during the ad hoc follow up of the EFF WG. The applicant provided additional efficacy data to demonstrate the influence of co-formulants to the efficacy of the products. According to this member the new data clearly show that at least three real products of this BPF that contain additional co-formulants are less efficacious than the tested reference product containing NaOCl and water only. Consequently, the tested reference product would not represent the minimum level of efficacy of the BPF and thus efficacy is not proven for the meta-SPCs containing these co-formulants. The rapporteur and the Chair of the EFF WG informed that the WG discussed this issue and concluded that these products were efficacious. The Chair concluded that the evaluation does not need to be amended.

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The opinion was adopted by majority. Two members (BE and DE) informed the BPC that they will file a minority opinion.

A member informed that they will submit a derogation to COM for several uses due to existing national legislation which requires an amendment of the conditions included in the SPC. COM informed about a document on requests for derogation scheduled for discussion at the CA meeting and asked MS to take this into consideration when requesting derogations.

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.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **Member (DE):** to submit the derogation to the Commission.
- **Member's minority (BE and DE):** to submit the minority position by **6 October 2022.**
- **SECR:** to forward the adopted opinion, minority position, draft SPC and final PAR to COM by as soon the necessary revisions of the documents can be handled and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **6 December 2022**.

8.6 Draft BPC opinion on an Union authorisation application for a biocidal product family containing active chlorine released from sodium hypochlorite for PT 2, 3, 4

The Chair welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case.

Taking into account that most of the open issues raised during the BPC consultation on this UA case are identical with the ones already discussed under the previous case (see point 8.5), the BPC agreed that there is no need to discuss the already discussed

comments with conclusions to be applied also for this case, except those on which different conclusion could be expected.

In contrary of the agreement reached for the previous case on the need for splitting of meta SPCs covering both ready-to-use (RTU) and concentrated products (for which the old BPF concept document is applied), several members noted that such splitting should be done for meta SPCs 66 and 129, which contain apart from RTU and concentrated products, also gel and liquid application types. The rapporteur explained that sufficient similarity in the products composition is seen within these meta SPCs, despite of differences in the formulation types and splitting is not needed from a risk perspective. It was, however noted that the usefulness of the SPC might be compromised. Subsequently, the Chair concluded that these meta SPCs need to be split.

The BPC also considered the applicant's proposal in the shared position paper and the further arguments presented for both applications (so under this and the previous agenda item), as regards the inclusion of a checklist for extension of the shelf-life of non-authorised or 'non-marketable' products (i.e. products with a shelf-life below 6 months). However, both the members and the SECR supported the view that is not possible to add such a checklist to the PAR. However, such a document will be useful in future pre-submission meetings. The SECR further noted that it is premature to consider already now what future guidance will be applicable when change applications for such products are submitted. As regards the applicant's request for clarification on whether unauthorised biocidal products could be re-introduced into the existing authorisation with a major change application, SECR explained that a request for classification of a change must be submitted first as it not possible at this point of time to indicate which type of change application is required. A member also noted that such approach to re-introduce products may not be applicable as for these applications the old BPF concept has been followed while new products may need to be treated under the new BPF concept.

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The opinion was adopted by the majority of the BPC members. Two members (from BE and DE) will submit a minority opinion.

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.
- **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.
- **Members' minority (BE and DE):** to submit the minority position by **6 October 2022**.
- **SECR:** to forward the adopted opinion, minority positions, draft SPC and final PAR to COM as soon the necessary revisons of the documents can be handled and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **6 December 2022**.

9. Article 75(1)(g) opinion requests

9.1. Draft BPC opinion on questions regarding the comparative assessment of anticoagulant rodenticides

The Chair informed the meeting about the background and process of the draft opinion followed a request submitted by COM to ECHA under Article 75(1)(g). This included the active involvement of stakeholders – also manufacturers of non-chemical alternatives – in the process which consisted among others of a targeted public consultation on the availability of non-chemical alternatives and a written consultation on a draft opinion. The SECR made a response to comments table available for the meeting including all comments provided during the written consultation. In addition, several documents provided by stakeholders during the written consultation were made available to the members and the involved stakeholders.

The Chair invited CEFIC/Biocides for Europe to introduce their socio-economic assessment. Biocides for Europe presented their draft socio-economic analysis (SEA) on the use of anticoagulant rodenticides, claiming that the use of AVK rodenticides is still be needed in the EU in an integrated Pest Management (IPM) approach where the issue is not if methods can replace but if methods are required to complement each other.

Futura explained the large increase of the market for rodent traps for several years, including in the food and pharma industry. Traps and IPM have now a primary role in leading food industry standards. Evidence of efficacy is generally available among user companies but not always disclosed. Additional field studies according to the NoCheRo guidance will be available in the coming months.

The Chair then addressed the overarching issues brought for discussion:

- Should the draft opinion adopt a broader perspective than the current draft ("SEA-like approach")?

The BPC agreed not to broaden the analysis, the burden being on the applicants of AVK rodenticides to demonstrate that their substance meets one of the conditions for derogation according to Article 5(2). No amendments of the draft opinion is therefore needed on this issue.

- Should the non-chemical alternatives be considered as separate modes of action (i.e. possibly compensating a lack of chemical alternatives with different modes of action)?

One member expressed support to the idea on the basis that non-chemical alternatives do not pose a risk of resistance. No other member's views were expressed. The Chair concluded that no changes would be made in the opinion regarding this issue, stating that a separate discussion would be needed to assess whether the current methodology on comparative assessment (as laid down in a Technical Guidance Note) needs to be amended.

- Should "humaneness" be added as a criterion for the assessment of alternatives?

One member mentioned that this is a criterion to be considered as indicated in the Technical Guidance Note on comparative assessment for biocidal products (paragraph 97, for non-chemical alternatives against vertebrate organisms: "The conditions under

which death occurs (e.g. unnecessary suffering, etc.)"), highlighting also that this criterion is directly linked to efficacy. Several other members supported the proposal to include this criterion. The Chair concluded that it will be checked how this could be taken into account in the present assessment, noting that the information would probably be very limited since only one field trial is available.

- Should "permanent baiting for brown and black rats and mice in and around buildings for trained professionals" be added as use #11?

One member indicated that permanent baiting is the most used technique as a preventive measure and should be assessed separately. Several other members indicated that permanent baiting is not allowed in their countries but supported the idea of considering it as a separate use. The Chair concluded that this new use will be added in the assessment.

- Should the Integrated Pest Management practice (IPM) be included in the assessment as an alternative of its own?

Several members and a stakeholder observer indicated that IPM should not be included in the assessment as an alternative of its own. Some members proposed that a recommendation for IPM could be introduced in the AVK rodenticides renewal opinion or in the AVK product authorisations. One member indicated that they have produced a guidance on IPM and intend to translate it in English. The stakeholder observer added that AVK rodenticides are not necessarily used as a last resort while applying IPM: this decision depends on the overall assessment of the case for the most effective rodent control.

- Should the Integrated Pest Management practice (IPM) be included in the assessment as an alternative of its own?

Several members and a stakeholder observer indicated that IPM should not be included in the assessment as an alternative of its own. Some members proposed that a recommendation for IPM could be introduced in the AVK rodenticides renewal opinion or in the AVK product authorisations. One member indicated that they have produced a guidance on IPM and intend to translate it in English. The stakeholder observer added that AVK rodenticides are not necessarily used as a last resort while applying IPM: this decision depends on the overall assessment of the case for the most effective rodent control.

- Should a distinction be made already now within the group of AVKs between FGAR and SCAR for the analysis of chemical alternatives?

Several members argued that the draft opinion – where such a distinction is not made – has to be amended as there is a significant difference in the hazard properties of both classes of AVKs. The SECR stated that this is in principle part of the remaining question included in the mandate ("question f") where a draft opinion will be discussed in the first Working Group meetings of 2023 with an intended adoption of the opinion in the second BPC meeting of 2023. SECR also informed that from the preliminary results of this analysis it is unclear if there are indeed such significant differences. In addition, the SECR referred to resistance occurring from the use of FGAR. It was concluded that the SECR will consider the comments made before and at the meeting on this issue. Several members indicated to submit further information on this issue to the SECR.

- Should Al phosphide be considered as a chemical alternative and carbon dioxide as an eligible chemical alternative.

The SECR explained the reasons for not considering Al phosphide as a chemical alternative which was agreed by the meeting. A member stated that they do not agree that carbon dioxide is not an eligible alternative as indicated in the draft opinion.

- Inclusion of human health risks in the comparison of eligible chemical alternatives with AVKs.

The SECR informed that – following comments of several members - human health risks will be included in the next version of the draft opinion.

- How to incorporate in the opinion the diverging views on non-chemical methods (traps)?

Several members and stakeholder observers reiterated their views on the suitability of rodent traps submitted during the third-party consultation which had been summarised in the draft opinion. On the one hand it is argued that traps alone cannot control rodents in all cases (including sometimes against mice inside buildings) and that both AVK rodenticides and non-chemical alternatives should be part of the IPM toolbox to be able to face all situations in a complementary manner. On the other hand, it is argued that efficacy of non-chemical methods has been proven in several instances e.g. by the switch by a large number of industries from AVK rodenticides to traps since several years and by field trials made according to the NoCheRo guidance (mice inside buildings – conform draft opinion). Both stakeholder observers supporting AVK rodenticides and traps indicated that additional field tests are on-going for and expected to be available by end of the year. No conclusion was reached in terms of how to integrate the diverging views in the BPC opinion.

- Should the BPC wait for the submission of the additional traps field studies for finalising its opinion?

The Chair highlighted the time constraints related to the present opinion on the comparative assessment of alternatives to AVK rodenticides which should be finalised before the second renewal of the AVK rodenticides. Bilateral discussions between the SECR and COM will be organised to agree on this issue.

- Are mice mechanical traps a suitable alternative for low (non-aggressive) as well as for medium and high (aggressive) infestations?

The Chair indicated that the field trail received and assessed for mice inside building relates to a medium infestation. A member highlighted that the efficacy guidance for active substances does not distinguish in levels of infestations therefore this aspect should not be considered either for evaluating non-chemical alternatives. The same applies to product authorisation where such issue is not taken into consideration. The Chair reminded that the infestation level issue was not brought only in relation with efficacy but also in relation with practical and economic disadvantages. One stakeholder observer mentioned that traps work for all levels of infestations also from an economical point of view, reason for several industries to switch several years ago. Another stakeholder observer mentioned that traps work in some cases but not all and that AVK rodenticides are still needed.

Actions:

- **SECR**: to amend the draft opinion and to distribute the presentation from Biocides for Europe;
- **Members:** to submit the requested information to the SECR.

10. Article 15(2) opinion requests

10.1 Draft BPC opinion on the review of approval of the active substance iodine and polyvinylpyrrolidone iodine

The Chair welcomed the applicant. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the dossier.

The applicant reiterated that there is an optimum for iodine and both deficiency and excess can lead to adverse effects (with deficiency being more problematic). In their view the follow-up should be a risk assessment, and they would like to have this reflected in the BPC opinion. For the applicant it is important to have the public document not only identifying the active substance as ED, but also including a statement that a risk assessment might need to be performed.

COM did not agree to already provide information in the BPC opinion on the next steps, as COM will discuss internally on the next steps to take after receiving of the BPC opinion. However, COM gave some indications on what the next steps may be, most likely:

- an analysis of alternatives, and/or;
- another mandate to ECHA for the risk assessment of iodine.

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The opinion was adopted by consensus.

Actions:

- **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 **21 October 2022** and publish it on the ECHA website.

11. Any other business

12. 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 44th meeting of BPC

26-29 September 2022

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 Website/Interact as part of the draft meeting minutes after the meeting.
Item 4 - Agreement of the minutes and review of actions from BPC-43	
The revised version of the minutes of BPC-43 was agreed.	**SECR:** to upload the agreed minutes to the BPC Interact and to the ECHA website.
Item 5 – Administrative issues	
The **Chair** informed the meeting that the intention is to organise the 22-24 November meeting as a face-to-face meeting.	
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 **13 October 2022**.
6.2 Update on active substance approval and Union authorisation	
The BPC took note of the presentation provided by the SECR and agreed on some of the questions raised in it.	**SECR:** to upload the presentation on Interact/BPC CIRCABC IG.
6.3 Proposal revision of working procedures for active substance approval and Union authorisation with respect to providing information during peer review	
The BPC discussed and agreed on the proposal by the FI member.	**SECR:** to revise the relevant BPC documents on providing new information during the peer review process for active substance approval and Union authorisation.

Item 7 - Applications for approval of active substances	
7.1 Validation of the PBT/vPvB or ED status of an active substance by the BPC with respect to the assessment whether the exclusion or substitution criteria are met	
The BPC discussed and agreed on the document provided by the SECR.	**SECR:** to upload the document on Interact/BPC CIRCABC IG.
7.2 Draft BPC opinion on Ozone generated from oxygen for PT 02, 04, 05 and 11	
The BPC adopted by consensus the opinion on the approval of the active substance for PT 2, 4, 5 and 11.	**Rapporteur**: to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR by **21 November 2022.** **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 **21 October 2022** and publish it on the ECHA website. **SECR:** to amend the combined LoEP and consult with the members from DE and NL.
7.3 Draft BPC opinion on Mecetronium ethyl sulphate (MES) for PT 01	
The BPC adopted by majority the opinion on the non-approval of the active substance for PT 01. Abstain: FR, IT, PL, RO Minority position : CZ	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **21 November 2022.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **Member (CZ):** to submit the minority position by **6 October 2022** **SECR:** to forward the adopted opinions to COM by **21 October 2022** and publish it on the ECHA website.
7.4 Draft BPC opinion on Sulphur dioxide generated from sulphur by combustion for PT 04	
The BPC adopted by consensus the opinion on the approval of the active substance for PT 04	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **21 November 2022.** **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 opinions to COM by **21 October 2022** and publish it on the ECHA website.

7.5 Draft BPC opinion on Sulfur dioxide released from sodium metabisulfite for PT 09	
The BPC adopted by consensus the opinion on the approval of the active substance for PT 09	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **21 November 2022.** **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 opinions to COM by **21 October 2022** and publish it on the ECHA website.
Item 8 – Union authorisation	
8.1 The applicant's involvement during the opinion forming process	
The BPC discussed the document provided by the SECR and agreed on option 1.	**SECR:** to revise and upload the document on Interact/BPC CIRCABC IG.
8.2 Guiding principles on handling information provided by the applicant during UA process	
The BPC took note of the document provided by the SECR.	**SECR:** to open a newsgroup for written comments with a dead-line of **21 October 2022**. **SECR:** to revise the document for the next BPC.
8.3 Draft BPC opinion on an Union authorisation application for a biocidal product family containing hydrogen peroxide for PT 2, 3, 4	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation. Abstain: BE	**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 **14 October 2022.** **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 **21 October 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **6 December 2022.**
8.4 Draft BPC opinion on an Union authorisation application for a biocidal product family containing peracetic acid for PT 3, 4	
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 **14 October 2022.** **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 **21 October 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **6 December 2022.**
8.5 Draft BPC opinion on an Union authorisation application for a biocidal product family containing active chlorine released from sodium hypochlorite for PT 2, 3, 4, 5	
The BPC adopted by majority the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **14 October 2022.** **Members (BE and DE):** to submit the minority position by **6 October 2022** **Member (DE):** to submit the derogation to the Commission. **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 **21 October 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **6 December 2022.**
8.6 Draft BPC opinion on an Union authorisation application for a biocidal product family containing active chlorine released from sodium hypochlorite for PT 2, 3, 4	
The BPC adopted by majority the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **14 October 2022.** **Members (BE and DE):** to submit the minority position by **6 October 2022** **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 **21 October 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **6 December 2022.**
Item 9 – Article 75(1)(g) opinion requests	
9.1 Draft BPC opinion on questions regarding the comparative assessment of anticoagulant rodenticides	
The BPC discussed the draft opinion on this request.	**Rapporteur:** to consult internally on the possibility to revise the draft opinion for discussion and adoption at BPC-45.

	SECR: to upload the presentations on Interact/BPC CIRCABC IG
Item 10 – Article 15(2) opinion requests	
10.1 Draft BPC opinion on the review of approval of the active substance iodine and polyvinylpyrrolidone iodine	
The BPC adopted by consensus the opinion.	**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 **21 October 2022** and publish it on the ECHA website.
Item 11 – Any other business	

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Part III - List of Attendees

Members		
AT	JOHN	Nina
BE	JARRETY	Helene
CH	BUEHLER	Dominique Anne
CZ	MIKOLAS	Jan
DE	TENTSCHER	Peter
DK	GREGERSEN	Nina Falk
EE	MERISTE	Anu
EL	VAGIAS	Vasileios
ES	GONZÁLEZ MÁRQUEZ	María Luisa
FI	KOIVISTO	Sanna
FR	CHEZEAU	Aurelie
HR	VRHOVAC FILIPOVIĆ	Ivana
HU	SZENTGYORGYI	Timea
IE	PIERCE	Louise
IT	BALDASSARRI	Lucilla
LT	HAKAITE	Palmira
LU	ZIGRAND	Jeff
LV	BROVKINA	Julija
NO	ESPEVIK RANDALL	Marit
PL	RZODECZKO	Helena
PT	BORGES	Maria Teresa
RO	DRAGOIU	Simona
SE	HAHLBECK	Edda
SI	CEBASEK	Petra
SK	MIKOLASKOVA	Denisa

Alternate members		
BE	LEROY	Celine
CH	PYTHON	Francois
FR	COLLET	Romy
MT	MALLIA	Lothar Paul
NL	KALKERS	Lucas

Advisors		
CH	MEIER	Margrith
DE	GEDUHN	Anke
DE	SEMISCH	Annetta
DE	FRIESEN	Anton
DE	KNEUER	Carsten
DE	BURKART	Corinna
DE	WINTRICH	Daniela
DE	SCHMOLZ	Erik
DE	EHNI	Markus
DE	ROITZSCH	Michael
DE	SCHÖPS	Ricardo
DE	JACOB	Stefanie
DE	JAEGER	Stefanie
DE	MATTHES	Susann
DE	MUHLE	Ulrike
DE	WEINHEIMER	Viola
ES	RUIZ LOPEZ	Elena
FI	VUORENSOLA	Katariina
FR	TALHOUËT	Anne-Claire
NL	HOLTHAUS	Karlijn
NL	LUIJK	Rebekka
NL	OTTO	Sander
NL	BOS	Carina
NL	KRUIDHOF	Sabine
PL	HUSZAŁ	Sylwester
SE	MOHAMMED	Ifthekhar Ali
SE	ASK BJÖRNBERG	Karolin
SK	CHMELIKOVA	Jana
SK	DRABOVÁ KUŠÍKOVÁ	Zuzana

Commission observers		
DG SANTE	CAINZOS GARCIA	Marta
DG SANTE	CHATELIN	Ludovic
DG SANTE	DELVAUX	Vincent
DG SANTE	GRUHN	Lena
DG SANTE	TSIAMIS	Konstantinos
EFSA observers		
EFSA	RINCON	Ana Maria
EFSA expert	WRIGHT	Matthew
Accredited Stakeholder Observers		
	AROZAMENA RAMOS	Eduardo
	AUBRY	Marc
	BARBU	Luminita
	COR	Gabrielle
	KAYASTH	Vedika
	LE LAIDIER	Gabriel
	MIHAI	Camelia
	SCHRÖER	Daniel
	VAN BERLO	Boris
	WEIß	Aharon
Applicants		
	AFEPASA	
	ARCHE Consortia	
	BODE Chemie GmbH	
	EuOTA / Exponent Inc	
	Micro-Pak Europe BV	
	Redebel Regulatory Affairs SCRL / Oxy'Pharm	
	SCC GmbH	
	WESSO AG	

ECHA Staff	
AIRAKSINEN	Antero
BUCHANAN	Camilla
CARLON	Claudio
DAMSTEN	Micaela
DE WOLF	Watze
ELO	Pertti
ESTEVAN MARTINEZ	Carmen
HÄMÄLÄINEN	Eva
HONKA	Anni
HYYTINEN	Eija-Riitta
KREBS	Bernhard
LAITINEN	Jaana
MACKEVICA	Aiga
MARCON	Eva
MOTTET	Denis
MUELLER	Gesine
RAULIO	Mari
ROCKE	Timo
STASKO	Jolanta
STRÖMBERG	Minna
SZANTO	Emese
SZYMANKIEWICZ	Katarzyna
UPHOFF	Andreas
VALKOVICOVA	Eva
VAN DE PLASSCHE	Erik
VAN DER LINDEN	Sander
VAN GALEN	Joost
VASILEVA	Katya
ZBIHLEJ	Thomas

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-44

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-44 meeting

Agenda Point	Number	Title		
2.	BPC-A-44-2022	Draft agenda		
4.	BPC-M-43-2022	Draft minutes from BPC-43		
5.1	-	Administrative issues and report from the other Committees		
6.1	BPC-44-2022-01	BPC Work Programme for active substance approval		
	BPC-44-2022-02	BPC Work Programme Union authorisation		
	BPC-44-2022-03	outlook for BPC		
	BPC-44-2022-04	outlook for BPC and ED assessment		
6.2	Presentation	Update on active substance approval and Union authorisation		
6.3	BPC-44-2022-21	Proposal revision of working procedures for active stance approval and Union authorisation with respect to providing information during peer review		
7.1	BPC-44-2022-05	Procedure for post approval data		
8.1	BPC-44-2022-13	The applicant's involvement during the opinion forming process		
8.2	BPC-44-2022-14	Guiding principles on handling information provided by the applicant during UA process		
11.	-	Any other business		
Agenda Point	**Number**	**Substance-PT**	**eCA**	**Title**
7. 2	BPC-44-2022-06A	**Ozone generated from oxygen PT 2, 4, 5 11**	NL	Draft BPC opinion
	BPC-44-2022-06B			Assessment report
	BPC-44-2022-06C			Open issues
	BPC-44-2022-06D			Combined LoEP ozone generated from oxygen (room document).
	BPC-44-2022-07A			Draft BPC opinion

	BPC-44-2022-07B	**Ozone generated from oxygen PT 4**		Assessment report
	BPC-44-2022-07C			Open issues
	BPC-44-2022-08A	**Ozone generated from oxygen PT 5**		Draft BPC opinion
	BPC-44-2022-08B			Assessment report
	BPC-44-2022-08C			Open issues
	BPC-44-2022-09A	**Ozone generated from oxygen PT 11**		Draft BPC opinion
	BPC-44-2022-09B			Assessment report
	BPC-44-2022-09C			Open issues
7.3	BPC-44-2022-10A	**Mecetronium ethyl sulphate (MES) PT 1**	PL	Draft BPC opinion
	BPC-44-2022-10B			Assessment report
	BPC-44-2022-10C			Open issues
7.4	BPC-44-2022-11A	**Sulphur dioxide generated from sulphur by combustion for PT 4**	DE	Draft BPC opinion
	BPC-44-2022-11B			Assessment report
	BPC-44-2022-11C			Open issues
7.5	BPC-44-2022-12A	**Sulfur dioxide released from sodium metabisulfite for PT 9**	DE	Draft BPC opinion
	BPC-44-2022-12B			Assessment report
	BPC-44-2022-12C			Open issues
8.3	BPC-44-2022-15A	**UA: hydrogen peroxide for PT 2, 3, 4**	NL	Draft BPC opinion
	BPC-44-2022-15B			SPC
	BPC-44-2022-15C			PAR
	BPC-44-2022-15D			PAR Conf Annex
	BPC-44-2022-15E			Open issues
8.4	BPC-44-2022-16A	**UA: peracetic acid for PT 3, 4**	DE	Draft BPC opinion
	BPC-44-2022-16B			SPC
	BPC-44-2022-16C			PAR
	BPC-44-2022-16D			PAR Conf Annex
	BPC-44-2022-16E			Open issues
	BPC-44-2022-16F			PAR MS Conf Annex
8.5	BPC-44-2022-17A			Draft BPC opinion

	BPC-44-2022-17B	**UA: active chlorine released from sodium hypochlorite for PT 2, 3, 4, 5**	FR	SPC
	BPC-44-2022-17C			PAR
	BPC-44-2022-17D			PAR Conf Annex
	BPC-44-2022-17E			Open issues
	BPC-44-2022-17F			Storage and chlorate formation. CH position paper.
8.6	BPC-44-2022-18A	**UA: active chlorine released from sodium hypochlorite for PT 2, 3, 4**	FR	Draft BPC opinion
	BPC-44-2022-18B			SPC
	BPC-44-2022-18C			PAR
	BPC-44-2022-18D			PAR Conf Annex
	BPC-44-2022-18E			Open issues
	BPC-44-2022-18F			Position paper
9.1	BPC-44-2022-19A	**Art 75 (1)(g): comparative assessment of anticoagulant rodenticides**	ECHA	Draft BPC opinion
	BPC-44-2022-19B			Response to comments ECHA written consultation draft BPC opinion
	BPC-44-2022-19C			CEFIC_BforE_Comparative review_control rodents
	BPC-44-2022-19D			CEFIC_BforE_Societal value Anticoagulant Rodenticides
	BPC-44-2022-19E			Futura_Case_futura
	BPC-44-2022-19F			Futura_Pest_control_Guideline
	BPC-44-2022-19G			SwissInno_Bewertungsbericht_SuperCat_Rattenfalle_Pro
	BPC-44-2022-19H			SwissInno_NSNT_Anerkennungsbescheid_UBA_18 IfSG_UBA-99 205-32_091120
	BPC-44-2022-19I			SwissInno_NSNT_Bewertungsbericht_UBA_18 IfSG_UBA-99 205-32_041120
	BPC-44-2022-19J			SwissInno_NSNT_Prüfbericht_UBA_18 IfSG_UBA-99 205-32_201020

	BPC-44-2022-19K			SwissInno_RF PRO_Anerkennungsbescheid_UBA_18 IfSG_250122
	BPC-44-2022-19L			SwissInno_RF PRO_Prüfbericht_UBA_205-21-5.1WR
	BPC-44-2022-19M			CEFIC_BforE_Socio-Economic Analysis for the use of Anticoagulant Rodenticides
	Presentation			Introduction ECHA
10.1	BPC-44-2022-20A	**Art 15(2):** **iodine and polyvinylpyrrolidone iodine**	SE	Draft BPC opinion
	BPC-44-2022-20B			Annex to the opinion
	BPC-44-2022-20C			Open issues

15 September 2022
BPC-A-44-2022_rev2

Draft agenda

44th meeting of the Biocidal Products Committee (BPC)

26-29 September 2022

Meeting is held virtually via WebEx

Starts on 26 September at 10:30, ends on 29 September at 18:00

The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-44-2022

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-43

BPC-M-43-2022

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-44-2022-01; BPC-44-2022-02; BPC-44-2022-03; BPC-44-2022-04

For information

6.2. Update on active substance approval and Union authorisation

For information

6.3. Proposal revision of working procedures for active stance approval and Union authorisation with respect to providing information during peer review

BPC-44-2022-21

For agreement

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

7.1. Validation of the PBT/vPvB status of an active substance by the BPC with respect to the assessment whether the exclusion or substitution criteria are met

BPC-44-2022-05

For agreement

7.2. Draft BPC opinion on Ozone generated from oxygen for PT 2, 4, 5 and 11

Previous discussion: WG-II-2022

BPC-44-2022-06A, B, C, D
BPC-44-2022-07A, B, C
BPC-44-2022-08A, B, C
BPC-44-2022-09A, B, C

For adoption

7.3. Draft BPC opinion on Mecetronium ethyl sulphate (MES) for PT 1

Previous discussion: WG-II-2022

BPC-44-2022-10A, B, C

For adoption

7.4. Draft BPC opinion on Sulfur dioxide generated from sulfur by combustion for PT 4

Previous discussion: WG-II-2022

BPC-44-2022-11A, B, C

For adoption

7.5. Draft BPC opinion on Sulfur dioxide released from sodium metabisulfite for PT 9

Previous discussion: WG-II-2022

BPC-44-2022-12A, B, C

For adoption

[5] For the discussions of the draft BPC opinions at least the following documents will be distributed: a draft BPC opinion (denoted by A), a draft assessment report (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).

8. – Union authorisation**

8.1. The applicant's involvement during the opinion forming process

BPC-44-2022-13

For agreement

8.2. Guiding principles on handling information provided by the applicant during UA process

BPC-44-2022-14

For discussion

8.3 Draft BPC opinion on an Union authorisation application for a biocidal product family containing hydrogen peroxide for PT 2, 3, 4

Previous discussion: WG-II-2022

BPC-44-2022-15A, B, C, D, E

For adoption

8.4 Draft BPC opinion on an Union authorisation application for a biocidal product family containing peracetic acid for PT 3, 4

Previous discussion: WG-II-2022

BPC-44-2022-16A, B, C, D, E, F

For adoption

8.5. Draft BPC opinion on an Union authorisation application for a biocidal product family containing active chlorine released from sodium hypochlorite for PT 2, 3, 4, 5

Previous discussion: WG-II-2022

BPC-44-2022-17A, B, C, D, E, F

For adoption

8.6. Draft BPC opinion on an Union authorisation application for a biocidal product family containing active chlorine released from sodium hypochlorite for PT 2, 3, 4

Previous discussion: WG-II-2022

BPC-44-2022-18A, B, C, D, E, F

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 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).

9. – Article 75(1)(g) opinion requests

9.1 Draft BPC opinion on questions regarding the comparative assessment of anticoagulant rodenticides

BPC-44-2022-19 A, B, C, D, E, F, G, H, I, J, K, L, M

For discussion

10.– Article 15(2) opinion requests

10.1 Draft BPC opinion on the review of approval of the active substance iodine and polyvinylpyrrolidone iodine

Previous discussion: WG-II-2022

BPC-44-2022-20 A, B, C

For adoption

11. - Any other business

12.– Action points and conclusions

Provisional time schedule for the

44th meeting of the Biocidal Products Committee (BPC)

Virtual meeting via WebEx

26 September 2022: starts at 10:30; 29 September 2022 ends at 18:00

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.

Monday 26 September: (starts at 10:30 EET/09:30 CET, ends at 18:00 EET/17:00 CET)

Items 1-5	Opening items and administrative issues
Item 6.1	BPC Work Programmes for active substance approval, Union authorisation, ED assessment and outlook for BPC
Item 6.2	Update on active substance approval and Union authorisation
Item 6.3.	Proposal revision of working procedures for active stance approval and Union authorisation with respect to providing information during peer review
Item 7.1	Validation of the PBT/vPvB status of an active substance by the BPC with respect to the assessment whether the exclusion or substitution criteria are met
Item 7.2	Draft BPC opinion on Ozone generated from oxygen for PT 2, 4, 5 and 11
Item 7.4	Draft BPC opinion on Sulphur dioxide generated from sulphur by combustion for PT 4
Item 7.5	Draft BPC opinion on Sulfur dioxide released from sodium metabisulfite for PT 9

Tuesday 27 September: (starts at 10:30 EET/09:30 CET, ends at 18:00 EET/17:00 CET)

Item 7.3	Draft BPC opinion on Mecetronium ethyl sulphate (MES) for PT 1
Item 10.1	Draft BPC opinion on the review of approval of the active substance iodine and polyvinylpyrrolidone iodine
Item 9.1	Draft BPC opinion on questions regarding the comparative assessment of anticoagulant rodenticides

Wednesday 28 September: (starts at 10:30 EET/09:30 CET, ends at 18:00 EET/17:00 CET)

Item 8.1	The applicant's involvement during the opinion forming process
Item 8.2	Guiding principles on handling information provided by the applicant during UA process
Item 8.3	Draft BPC opinion on an Union authorisation application for a biocidal product family containing hydrogen peroxide for PT 2, 3, 4 (BC-HC029658-43)
Item 8.4	Draft BPC opinion on an Union authorisation application for a biocidal product family containing peracetic acid for PT 3, 4 (BC-QN034236-29)

Thursday 29 September: (starts at 10:30 EET/09:30 CET, ends at 18:00 EET/17:00 CET)

Item 8.5	Draft BPC opinion on an Union authorisation application for a biocidal product family containing active chlorine released from sodium hypochlorite for PT 2, 3, 4, 5 (BC-HQ045419-21)
Item 8.6	Draft BPC opinion on an Union authorisation application for a biocidal product family containing active chlorine released from sodium hypochlorite for PT 2, 3, 4 (BC-LK045398-25)
Item 11	Action points and conclusions

End of meeting

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