Final non-confidential minutes of the 49th meeting of the Biocidal Products Committee (BPC)

21-23 November 2023 &
12 December 2023

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
1. Welcome and apologies	
Minutes: The Chair of the Biocidal Products Committee (BPC), welcomed the participants to the 49th BPC meeting which took place as a hybrid meeting in ECHA and in WebEx. The Chair then informed the BPC members of the participation of 28 members, including two alternate members. 28 Advisers and four representatives from an accredited stakeholder organisation (ASO) were present at the meeting. Six observers from the European Commission attended the meeting. Applicants were invited and present for their specific substances under agenda item 7, biocidal products under agenda item 8, Article 38 under agenda point 9 and Article 75(1)(g) item under agenda point 10 where details are provided in the summary record of the discussion for the cases and in Part III of this document.	
2. Agreement of the agenda	
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 this document.	
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.
3. Declarations of potential conflicts of interest to the agenda	
Minutes: 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 minutes and review of actions from BPC-48	
Minutes: The Chair mentioned that all actions from the previous BPC-48 meeting were carried out.	
The revised confidential and non-confidential draft minutes from BPC-48 (BPC-M-48-2023), incorporating the comments received, were agreed.	**SECR:** to upload the agreed confidential minutes to the BPC Interact and non-confidential minutes to the ECHA website.

5. Administrative issues

Minutes: The **Chair** informed the meeting that the February meeting will be virtual, provisional dates being Mon-Tue 26-27 and Thu 29 February 2024.

The members and observers were reminded to register timely.

The members were informed that more structured open issues tables will be used for AS & UA cases from the next meeting onwards.

The members were informed on logo on the opinions (lay out of opinion template will be revised later). Furthermore, the UA opinion template will contain a table with the authorised uses.

6. Work programme for BPC

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

Minutes: The Chair informed the members that the Work Programme for active substance approval and Union authorisation were revised after the last BPC meeting. Based on inputs following BPC-49 the AS WP will be updated again and published on our website.

The Chair showed the slide with the foreseen AS, UA and Article 75 (1)(g) opinions for the BPC meeting in February 2024 and asked the involved eCAs to inform the SECR accordingly.

The Chair also informed on the timelines of finalising the opinions agreed during this meeting and submission to the Commission.

-	**Members:** to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by **7 December 2023.**

6.2 Update on active substance approval

Minutes: The SECR provided an update on the active substance approval process (AS).

The SECR informed about the AS dossiers in the opinion forming process and about expected new submissions for opinion. The SECR remarked the inaccuracy of the planning provided by Member States and reminded the members to keep the planning document updated in the Interact Collaboration tool, especially on the newly added overview of the ED assessment.

The SECR and the Commission expressed concerns on the general progress of the Review Programme. Member States were reminded to implement the actions agreed at the CA meeting and in the ECHA Active Substance Action Plan, with especial attention on backlog dossiers for which decisions (still under the BPD) are becoming more and more challenging. The Commission remarked the usefulness of having a rolling planning for the on-going year and the next year, considering also that Member States provided forecasts to ECHA.

The SECR also reported on the second information session for evaluating CAs held on 26 October 2023, with around hundred participants. The session consisted in three topics proposed by the CAs: how to request new data, the renewal of active substance approval and one substance one assessment.

The BPC took note of the presentation provided by the SECR.	**SECR:** to upload the presentation on Interact. **Members:** to update the Interact Collaboration on the progress of the active substance cases by 7 December and to keep it updated in the future.

6.3 Update on Union Authorisation processes

Minutes: An update on Union authorisation (UA) and related processes was given by the SECR. The SECR presented the current workload of UA dossiers in the opinion forming process as well as historical data form 2022 and 2023. The SECR also updated the BPC on the workload in relation to the same biocidal products and changes applications.

The SECR remarked the inaccuracy of the planning provided for the UA applications for the next year and reminded the members to keep the planning document updated in the Interact Collaboration tool. In addition, SECR informed that new tab is created in the Excel file that the evaluating competent authorities (eCA) can provide information on the submission of the conclusions for the opinion forming process for UA-MAC applications.

In relation to the planning and general coordination the SECR proposed for the eCAs to establish the UA contact points. The MSs were invited to consider whether they would support such initiative and to inform the BPC SECR on their appointed contact points within 2 weeks after the BPC meeting.

During the meeting the SECR provided a list of the procedural documents which will be updated to:

a) to address the change from the SPC Editor to the SPC in IUCLID,

b) include the date of applicability of the documents.

During the meeting, the COM asked the SECR to provide update on the preparation of the file with status of UAs in the different steps of the procedures. The SECR explained that work is ongoing and data obtained from the systems are under validation.

The SECR informed the BPC of a new COM's proposal where, for UA same biocidal products in parallel (UA-BBP), the same biocidal product applicants would be provided with the final SPCs of the reference product prior to the authorisation of the same biocidal product. The same biocidal product applicant would simply be requested to implement their administrative change without the need to liaise with the authorisation holder of the reference UA to obtain the final SPCs. The MSs and ASOs were invited to consider whether they would support such initiative and to inform the BPC SECR within 2 weeks after the BPC meeting.

The BPC took note of the presentation provided by the SECR.	**SECR:** to upload the presentation on Interact. **Members:** to update the Interact Collaboration on the progress of the union authorisation by 7 December and to keep it updated in the future. **Members:** To send contact point details to the SECR.

6.4 Update on article 75(1)(g) mandates

Minutes: An update was given by the SECR on the status of the currently ongoing Article 75 (1)(g) mandates.

a) Workload

The SECR presented an overview on the number of mandates received for which work is ongoing, and the expected timeline for which their opinions will be discussed at BPC. SECR highlighted that many of the mandates result in more than one BPC opinion. Currently there are:

- 7 mandates for which work is ongoing
    - From which hopefully 2 will be finalised at this meeting with the adoption of two opinions: Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides and Evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)

- 3 mandates arrived new this year, 2023
- 2 of the seven remain open from before 2020. One is related to the bee guidance for which the adoption is expected for this meeting, the other mandate is related to the clarification of endocrine disruption properties for several active substances, from which assessment and opinion adoption remains only for two.

- 5 expected mandates to arrive
- 9 finalised mandates in the last 3 years: 2 were finalised in June 2023, 3 in 2022 and 5 in 2021.

b) Reasons behind the Article 75(1)(g)

The SECR presented an overview on the reasons behind requesting Article 75(1)(g) mandates, focusing on the ongoing mandates. The active mandates aim to clarify:

- ED properties
- Analysis of Alternatives
- General scientific questions
- Case specific guidance development/revision
- Verification of consistency of opinions
- Further investigation of efficacy

The BPC took note of the presentation provided by the SECR.	**SECR:** to upload the presentation on Interact.

7. Applications for approval of active substances

7.1 Revised working procedure active substances

Minutes: The SECR presented the updated version of the working procedures for active substances after the feedback received from the BPC. The main changes in version 9.0 of the working procedure consist of clearer and simplified text, with specific indication of the applicability date; and early set in the process of the consultation on candidates for substitution to allow a better assessment of potential alternatives; and the inclusion of the procedure for full and limited evaluation renewals of the approval.

The document agreed at the meeting, was published on ECHA website (BPC site) at the beginning of December 2023, replacing the existing version of the working procedure.

The BPC agreed on the document provided by the SECR.	**SECR:** to upload the document on Interact.

7.2 Draft BPC opinion on Bronopol for PT 2, 11, 12

The Chair welcomed the APPL for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case. The Chair emphasised the importance of having a unambiguous conclusion in the opinion on whether an active substance can be approved or not, which should be in line with the conclusions at the Working Groups. Subsequently the issues identified in the Open Issues Table were discussed.

<u>The assessment report</u>

The data gap for gene mutation was discussed and the BPC concluded that the provided UDS assay is no longer acceptable to fill that gap, therefore a conclusion on genotoxicity is not possible. The data gap was identified during the commenting phase.

BPC members pointed out that a discussion is ongoing at the CA meeting for the substances of the Review Programme where the COM proposed to postpone the ED assessment for environmental NTOs until renewal stage if the substance has no HH ED properties. However, this can only be implemented

after this is agreed at the CA meeting and confirmed by the COM's legal service. In light of this discussion, the BPC members were in favour to focus in the opinion on the lacking conclusion for genotoxicity as one of the main reasons for the non-approval approval, rather than the lacking ED ENV conclusion and the fact that the ENV risk assessment cannot be finalised.

The APPL claimed that as there is a negative carcinogenicity study, there is no concern for mutagenicity. For the ENV, all requested studies were performed and delivered before submission of the CAR to ECHA. It was explained to the APPL that mutagenicity is a stand-alone endpoint, and a negative carcinogenicity study is not covering a positive mutagenicity test. It further was pointed out that the submitted ENV data were of poor quality, with deviations from guidelines and therefore it was not possible to conclude on ED properties for NTOs.

COM indicated that the Assessment Report should contain a clear explanation why it was not possible to conclude on mutagenicity and ED NTO. Thereby referring to the legal provisions and timelines followed in the process, also reflecting on the consequences for the outcome of the risk assessment.

It was concluded that the assessment report will be amended to include a detailed explanation on how the conclusions for mutagenicity and ED for NTO were reached.

There was an exchange on the timelines of requests for additional information in which eCA and the APPL provided their recollections from this process. Upon request from COM, it was explained that a mutagenicity test (GMMC) *in vitro* test was not requested by the HH WG as it is not realistic that such a test could be performed within 10 working days after the WG, as required by the published BPC document "New information in active substance and Union authorisation opinion forming". There were further reflections that the validity of the UDS test was scientifically questioned for a longer time, and this has been reflected in the newly adopted guidance.

An exchange took place on the conclusions with regards to ED criteria for NTO's. The text was amended to reflect the process and the introduction of a Weight of Evidence (WoE) approach to solve the data gap, thereby noting that there are different recollections from eCA and the APPL.

<u>Opinion PT2</u>

It was noted that most of the open issues on the opinion for PT2 are valid for the opinions on PT11 and PT 12 as well and therefore these opinions need to be amended accordingly.

There were extensive discussions on the exact wording of the opinion. It was agreed that the text for mutagenicity as proposed for the assessment report will be included in the opinion as well.

The BPC members agreed that the conclusions for HH, ENV and the overall conclusions in the opinion should reflect the outcome of the risk assessment, meaning a non-approval of the active substance for PT2. It was agreed that the opinion had to be completely amended accordingly.

The APPL requested to postpone the process, since they were willing to conduct new studies, which will have to be considered for those PTs still under evaluation. It was explained that this is not possible in this phase of the process since the opinion forming phase should be finalised within the legally defined period of 270 days.

<u>Opinion PT11</u>

It was discussed by the BPC members to have a traditional risk assessment for ENV and a separated ED risk assessment. It was agreed to align the text in the opinion with the text in the PT2 opinion for the general parts. The table with conclusions of the risk assessment and the footnotes were amended separately, the text of the conclusions was aligned with the PT2 opinion. For the HH risk assessment tables, it was agreed to include a conclusion for the application scenarios and to mention that these are covered by the results for the post-application scenarios.

<u>Opinion PT12</u>

BPC members agreed that all the revisions proposed for PT2 were also implemented for PT12. The conclusions on efficacy were slightly amended, it was agreed that the rest of the opinion should be

aligned with the PT2 opinion. As for PT 11, it was agreed to include to the HH risks assessment a conclusion for the application scenarios.

All opinions were amended overnight and the discussion resumed the next day on these amended opinions.

Amended opinion PT2

COM requested a clarification on the WoE approach and the connection to the publication of new guidance and BPR annexes.

The APPL questioned the non-approval because of the potential mutagenicity claiming that as the carcinogenicity study is negative, there is no concern for mutagenicity. It was explained that mutagenicity and carcinogenicity are two separated endpoints.

BPC members and SECR agreed to amend the text to reflect that, in line with changes in the guidance and the opinion of scientific community, the sensitivity and relevance of the UDS test was questioned by the WG. Therefore the data for mutagenicity is insufficient to conclude.

The conclusions in HH summary table were adjusted for all scenarios in line with a previous BPC opinion. COM proposed adjusting the text after the table to reflect and explain the conclusions in the table and the fact that it was not possible to conclude on the acceptable risk due to the data gap for mutagenicity.

It was agreed to bring the conclusions in the summary table of ENV scenarios in line with the conclusions in the summary table on HH as far as it makes sense.

BPC members agreed on removing the first two paragraphs on the traditional risk assessment, leaving only the ED part.

The eCA and the APPL discussed the communication which has taken place before and during the opinion forming process; it was concluded that the parties did not agree on the either the content or sequence of these discussions.

As a general issue BPC members mentioned that it would facilitate the discussion if ad hoc follow-up conclusions and WGs minutes would be available prior to the BPC meeting.

Since it was not possible to agree on the opinions at this meeting, it was agreed that eCA and ECHA would revise the opinions, organise a written consultation and discuss at an additional (virtual) meeting day on 12 December.

All opinions were amended following the written consultation and the discussion resumed on 12 December on these amended opinions.

It was agreed that the explanations of the procedure for the assessment of mutagenicity and ED for NTO would be removed from the opinion and rather be incorporated in the CAR. It was explained to the APPL that this was done to keep the opinions in line with previous opinions and the CAR will contain an overview of the most important points of the process.

The APPL provided his remarks about the process, in particular on their responsibility to deliver the complete dossier. It was explained that it is very clear that the APPL is responsible for a complete and compliant dossier upon application. During the evaluation the eCA may ask for additional information, it is the responsibility of the APPL to provide the required information in a timely way. In addition, it was explained that the initial proposal by the eCA may change during the opinion forming phase, there is only a limited possibility to provide additional information during this phase.

The APPL reminded their willingness to provide new data and informed that several tests are already ongoing, they asked for a possibility to stop the process until the new data is available. SECR responded that there is no legal possibility to stop the process and provide data at this phase of the process.

BPC members and COM discussed what should be included in the overall conclusion as the main reason for non-approval. Overall conclusions, harmonized with previous opinions were agreed by the BPC.

COM requested further explanations why the data gap for ED ENV was not taken into account as the ground for non-approval as ED ENV data is a core data set. However, BPC members concluded that the data gap for mutagenicity was the main ground for not being able to conclude on the exclusion criteria and for the conclusion of non-approval, therefore this should be focus of this opinion.

COM requested to record in the minutes their concern about not considering the ED for NTO data gap and the inability to conclude on safe use of the active substance (due to the data gaps on ED and mutagenicity) as a reason for non-approval. Some members voiced their concerns with regards to the process during the evaluation phase.

It was explained that the opinions will be updated in accordance with the agreements on the open issues as discussed during all three days.

The BPC <u>discussed</u> the opinion on the approval of the active substance for **PTs 2, 11, 12 and agreed on the following steps.**	**SECR:** to distribute the document on the next steps to finalise the bronopol opinions. **Members, SECR and rapporteur:** to take note of these steps and to provide their input within the relevant timelines. **SECR:** to organise **a virtual BPC meeting** on **12 December** and inform the members accordingly.
<u>Follow-up day 12 December 2023</u> The BPC <u>adopted by consensus</u> the opinion on the non-approval of the active substance for **PTs 2, 11, 12.** (ES, FI, IT PT abstained)	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **24 January**. **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 **19 December** and publish them on the ECHA website.

8. Union authorisation

8.1 Linguistic review procedure for Union authorisation and major changes applications of a Union Authorisation

Minutes: The SECR presented the revised procedure for linguistic review of the translations of the summary of product characteristics for Union authorisation applications. The following main changes were incorporated:

a) to address major changes application process,

b) implementation of the SPC in IUCLID,

c) inclusion of the date of applicability in the version history of the document,

d) adding the step 5 to clarify procedure after the SECR transmits the final translations of the SPC to the COM.

During the meeting the COM noted that Section 2 of the document have to be updated to make it clear that the translations (when available) from the glossary of frequently used sentences need to be used in the SPC. Moreover, the COM reminded the BPC that all text in the SPC (except trade names and addresses) have to be translated, it applies also to the text included in the Section 6 of the SPC.

One BPC member asked whether the parts which are updated in the SPC based on the major changes or minor changes applications can be highlighted. The SECR explained that changes in the SPC can be

identified by using the comparison tool available in the SPC editor and SPC in IUCLID.	
The BPC agreed on the document provided by the SECR.	**SECR:** to upload the document on Interact.

8.2 Working procedure for minor change applications of a Union authorisation and supporting documents for administrative changes and same biocidal products of Union authorisation

Minutes: The SECR presented the revised procedure for minor change applications to UAs (UA-MIC). The following main changes were incorporated:

a) Addition of criteria for the request of data under step 5.

b) Clarifications on the applicant's role during commenting included.

c) Clarifications included when the discussion and agreement step is not carried out.

d) Clarifications on the vote by written agreement included to opinion forming.

e) Durations of steps 7 and 10 modified.

f) Transition from SPC Editor to dedicated configuration of SPC in IUCLID.

g) Update of flowchart

In addition, the SECR provided a presentation to clarify the commenting and decision step of UA-MIC, which considerably differ in their implementation compared to the same steps for UA applications. Improvements to the opinion forming step were also discussed during the meeting. It was proposed to shorten the time dedicated to the vote by written procedure for the adoption of BPC opinions in the context of UA-MIC from 15 to 5 days since i) no comments can be provided during that step and ii) based on experience the majority of the vote were casted on the last day, leading to uncertainty whether the quorum would be reached. BPC members expressed the opinion that 5 days is too short. Instead, it was agreed that the BPC members will have 10 days to cast their votes on UA-MIC BPC opinions. Should the quorum not be reached after 10 days, ECHA will send a reminder to the BPC members to cast their vote until day 15. One BPC member reminded the other BPC members to be committed to actively vote on UA-MIC BPC opinions, which would resolve the issue related to reaching quorum.

The SECR also presented revised versions of the supporting documents for notifications of administrative changes to UA (UA-ADC) and same biocidal products of UA (UA-BBP/UA-BBS). It was highlighted that the supporting documents had been separated from the corresponding supporting documents for national applications.

The BPC agreed on the document provided by the SECR.	**SECR:** to upload the document on Interact.

8.3 Draft BPC opinion on a Union authorisation application for a biocidal product containing Propan-1-ol and Propan-2-ol for PT 1

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

At the request of a BPC member, a summary of the dietary risk assessment will be added to the conclusion of the PAR and of the BPC opinion.

Several comments were made on the wording of the application methods, rate, and frequency in the direction for use part of the PAR. The Chair presented a proposal he had made to clarify this part of the PAR. The eCA and the COM confirmed their agreement with the proposal.

An extensive discussion took place on the need to refine the wording of an RMM agreed at the WG meeting. Two BPC members expressed concerns about how to indicate that the product should be used in a separate area to protect children and toddlers and more generally people from prolonged exposure

to high concentrations of alcohol vapour. During the discussion, a new proposal for the RMM phrase was drafted and agreed by the BPC members.

One BPC member expressed a concern regarding decanting and refilling of products used as surgical handrub. This concern was shared by the BPC. The APP clarified that refilling or decanting of the products is not intended. Therefore, a sentence prohibiting decanting and refilling of products used as surgical handrub was added to the SPC.

The COM raised issues related to the use of the SPC editor that are relevant for the drafting and publication of the act and its annex. The issues raised were discussed in a follow-up bilateral meeting with ECHA in order to ensure that the COM receives the SPC version it wants.

All points in the table of open issues were addressed and the conclusions reached were recorded in the table of open issues. The BPC members agreed to amend the draft PAR, the draft SPC and the BPC opinion according to the discussion.

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 **11 December 2023.** **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 **19 December 2023** and publish the opinion on the ECHA website.

8.4 Draft BPC opinion on a Union authorisation application for a biocidal product containing Propan-2-ol for PT 2

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

For the redacted PAR, the issue of embedded files and their accessibility upon conversion to a pdf file has been discussed. It has been explained by the BPC Chair that GC discussion is ongoing in relation to this topic, and it is technically possible to embed files to a pdf file. Further, it has been reminded that embedded files should not contain confidential information, and this should be part of the confidential annex.

The use of wipes in the use called "mopping" has been explained by the applicant where the use describes a situation when large wipes are used for mopping the floor. Therefore, the use-specific instructions for use should remain referring to wipes instead of mops. One member state (CH) disagreed with this conclusion.

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 **11 December 2023.** **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 **19 December 2023** and publish the opinion on the ECHA website.

8.5 Draft BPC opinion on a Union authorisation application for a biocidal product family containing Active chlorine released from calcium hypochlorite for PT 2, 3	
Minutes: The Chair welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The eCA briefly introduced the case. With regard to the eCA's proposal to verify and accept the additional data on metal corrosion endpoint that complement the data requested and evaluated by the APCP WG, several members expressed their support to it, noting that: • the requested new data has been provided within 10-day period after the WG meeting, evaluated and verified by the APCP WG in an ad hoc follow-up, in accordance with the BPC procedure, • the additional data presented prior to the BPC for follow-up clarification has only confirmed the APCP WG expectations, based on the interim test results. The applicant provided further clarification on this point, noting that the initial dataset provided within this UA application had metal corrosion data on Meta-SPC1 only with proposed read across to Meta-SPC2. Following the first indications during commenting for the need for further data on this endpoint, the testing has been initiated and the study results have become available shortly after the APCP WG meeting. However, no clear evidence of corrosion has been seen for Meta-SPC2, as assumed, from the uniform corrosion study. Therefore, there was a need to continue the complementary localised corrosion depth determination in another lab, where the Meta-SPC2 product showed clearly evidence for metal corrosion. Taking this into account and following the verification of the final study report, the BPC members agreed on the classification of Meta-SPC2 as corrosive to metals. As regards the additional data on efficacy generated during the case's peer review, but neither requested, nor accepted by the EFF WG, the members concluded in line with the agreed procedure, i.e. not to accept such non-verified data at this stage of the proceeding. The applicant noted that the potential shelf-life extension (based on the newly generated data) is a significant issue from customer-based perspectives, but also recognised the procedural difficulties with new information submission during the BPC opinion-forming stage and the reasoning of this BPC conclusion. As the applicant informed about its intention to submit a change application following the authorisation of the BPF, the members were asked for further advice on its preparation. The applicant was recommended to liaise with the eCA for this UA or any other prospective eCA that would agree to assess the future change application to get more clarification on data needed and the potential early consultation options. All items in the open issues table were addressed and conclusions reached were recorded in the open issues table.	
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 **11 December 2023.** **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 **19 December 2023** and publish the opinion on the ECHA website.
9. Article 38 opinion requests	
9.1 Draft BPC opinion on Unresolved objections during a mutual recognition procedure for a PT18 biocidal product against poultry red mite, stable fly and darkling beetle	

Minutes: 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 BPC agreed with the proposals in the open issue table. The chair explained that, as article 38 are product specific by definition, the BPC opinion will not state that the conclusion is valid for this product only as this would be superfluous.	
The BPC adopted by consensus the opinion.	**Rapporteur:** to revise the draft opinion in accordance with the discussions in the BPC and submit to the SECR by **11 December 2023.** **SECR:** to forward the adopted opinion to COM by **19 December 2023** and publish the opinion on the ECHA website.
10. Article 75(1)(g) opinion requests	
10.1 Draft BPC opinion on Evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)	
Minutes: The Chair welcomed the applicant for this second discussion on this item. The ASOs were 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. Members acknowledged the extensive work performed by the Rapporteur. Some members raised a more general concern about the challenges pertaining to conducting analysis of alternatives at the stage of the first active substance approval, in particular the difficulty to draw assertive conclusions on the availability of suitable alternatives due to the lack of detailed information, as no products have been authorised under the BPR yet for products containing the active substances under investigation, nor for possible alternative active substances. These members called for more extensive discussions in different scientific and political fora to address these general issues and other methodological issues (e.g. on the possibility to set up a hierarchy of classifications if a comparison of the risks is not possible or on how compare uses where for one active substance a device is needed, for the alternative one not). Some members called for an uphold of the adoption of the present opinion on the alternatives to RP1:1 and RP3:2 until such general discussions have taken place and the issues resolved. However, the Commission clarified that such discussions would take a long time and would significantly delay the adoption of the opinion if such an approach was taken. One member reminded the COM that a long delay has already been caused by the COM's request to investigate the ED properties although both substances have already fulfilled other exclusion criteria. In light of these circumstances, this member does not understand the pressure that the Commission is now exerting on the BPC to come to a conclusion on alternatives despite insufficient information. It was finally agreed that a new paragraph would be added in the opinion (with drafting support from DE and SE), reflecting the uncertainties affecting its conclusions and highlighting the need for broader discussions on the issue of analyses of alternatives at active substance approval level.	
The BPC adopted by consensus the opinion.	**SECR:** to amend the draft opinion in accordance with the discussions in the BPC and to liaise with DE and SE on an additional paragraph to the opinion. **Members DE & SE** to revise the proposal to amend the opinion. **SECR:** to forward the adopted opinion to COM by **19 December 2023** and publish the opinion on the ECHA website.

10.2 Draft BPC opinion on Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides	
Minutes: The ASOs were allowed to be present during the discussion. The SECR presented an overview on the draft ECHA guidance for the risk assessment of bees from the use of biocides ("ECHA Bee guidance"), which provides applicants and competent authorities with the methodology to assess the risk to honeybees, bumble bees and solitary bees from the use of biocidal products. The ECHA Bee guidance takes into account the available guidance for plant protection products (EFSA 2023), having made the necessary adaptations to biocides when needed. With regards to arthropod pollinators other than bees, future development of guidance is needed since at the time of the preparation of this guidance sufficient information was not available for developing a risk assessment methodology for non-bee pollinators. In the written consultation by the BPC members a suggestion was made to already at this point revise the risk mitigation phrases available for plant protection products and provide sentences specific to biocides. However, the development and agreement of e.g. frequently used sentences for SPC are not discussed by the BPC and instead are addressed via the Coordination Group. COM furthermore highlighted the need to align the sentences as far as possible with the ones used in the PPPs. In addition, more time will be needed to gain experience to discuss specific sentences for biocidal products. The ECHA Bee guidance will provide a general description of the currently available information with regards to risk mitigation measures. With regards to a comment on the general complexity of the guidance, ECHA noted that in the implementation stage support will be provided to member state authorities and industry. Being a Commission mandate to the BPC (pursuant BPR Art. 75(1)g), the guidance is finalised in the form of the BPC Opinion. Next, the guidance document will proceed to editorial finalisation with an expected publication in Q1/2024 the latest.	
The BPC adopted by consensus the opinion.	**SECR:** to revise the draft opinion in accordance with the discussions in the BPC. **SECR:** to forward the adopted opinion to COM by **19 December 2023** and publish the opinion on the ECHA website.
11. Any other business	
12. Action points and conclusions	

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Part II - Main conclusions and action points

Agreed at the 49th meeting of BPC

21-23 November 2023 &
12 December 2023

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
1. Welcome and apologies	
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.
3. Declarations of potential conflicts of interest to the agenda	
4. Agreement of the minutes and review of actions from BPC-48	
The revised confidential and non-confidential draft minutes from BPC-48 (BPC-M-48-2023), incorporating the comments received, were agreed.	**SECR:** to upload the agreed confidential minutes to the BPC Interact and non-confidential minutes to the ECHA website.
5. Administrative issues	
The **Chair** informed the meeting that the February meeting will be virtual, provisional dates being Mon-Tue 26-27 and Thu 29 February 2024. The members and observers were reminded to register timely. The members were informed that more structured open issues tables will be used for AS & UA cases from the next meeting onwards. The members were informed on logo on the opinions (lay out of opinion template will be revised later).	
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 **7 December 2023.**

6.2 Update on active substance approval	
The BPC took note of the presentation provided by the SECR.	**SECR:** to upload the presentation on Interact. **Members:** to update the Interact Collaboration on the progress of the active substance cases by 7 December and to keep it updated in the future.
6.3 Update on Union Authorisation processes	
The BPC took note of the presentation provided by the SECR.	**SECR:** to upload the presentation on Interact. **Members:** to update the Interact Collaboration on the progress of the union authorisation by 7 December and to keep it updated in the future. **Members:** To send contact point details to the SECR.
6.4 Update on article 75(1)(g) mandates	
The BPC took note of the presentation provided by the SECR.	**SECR:** to upload the presentation on Interact.
7. Applications for approval of active substances	
7.1 Revised working procedure active substances	
The BPC agreed on the document provided by the SECR.	**SECR:** to upload the document on Interact.
7.2 Draft BPC opinion on Bronopol for PT 2, 11, 12	
The BPC <u>discussed</u> the opinion on the approval of the active substance for **PTs 2, 11, 12 and agreed on the following steps.** **<u>On 12 December 2023</u>** The BPC <u>adopted by consensus</u> the opinion on the non-approval of the active substance for **PTs 2, 11, 12.** (ES, FI, IT PT abstained)	**SECR:** to distribute the document on the next steps to finalise the bronopol opinions. **Members, SECR and rapporteur:** to take note of these steps and to provide their input within the relevant timelines. **SECR:** to organise **a virtual BPC meeting** on **12 December** and inform the members accordingly. **Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **24 January**. **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 **19 December** and publish them on the ECHA website.

8. Union authorisation	
8.1 Linguistic review procedure for Union authorisation and major changes applications of a Union Authorisation	
The BPC agreed on the document provided by the SECR.	**SECR:** to upload the document on Interact.
8.2 Working procedure for minor change applications of a Union authorisation and supporting documents for administrative changes and same biocidal products of Union authorisation	
The BPC agreed on the document provided by the SECR.	**SECR:** to upload the document on Interact.
8.3 Draft BPC opinion on a Union authorisation application for a biocidal product containing Propan-1-ol and Propan-2-ol for PT 1	
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 **11 December 2023.** **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 **19 December 2023** and publish the opinion on the ECHA website.
8.4 Draft BPC opinion on a Union authorisation application for a biocidal product containing Propan-2-ol for PT 2	
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 **11 December 2023.** **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 **19 December 2023** and publish the opinion on the ECHA website.
8.5 Draft BPC opinion on a Union authorisation application for a biocidal product family containing Active chlorine released from calcium hypochlorite for PT 2, 3	
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 **11 December 2023.** **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 **19 December 2023** and publish the opinion on the ECHA website.
9. Article 38 opinion requests	
9.1 Draft BPC opinion on Unresolved objections during a mutual recognition procedure for a PT18 biocidal product against poultry red mite, stable fly and darkling beetle	
The BPC adopted by consensus the opinion.	**Rapporteur:** to revise the draft opinion in accordance with the discussions in the BPC and submit to the SECR by **11 December 2023.** **SECR:** to forward the adopted opinion to COM by **19 December 2023** and publish the opinion on the ECHA website.
10. Article 75(1)(g) opinion requests	
10.1 Draft BPC opinion on Evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)	
The BPC adopted by consensus the opinion.	**SECR:** to amend the draft opinion in accordance with the discussions in the BPC and to liaise with DE and SE on an additional paragraph to the opinion. **Members DE & SE** to revise the proposal to amend the opinion. **SECR:** to forward the adopted opinion to COM by **19 December 2023** and publish the opinion on the ECHA website.
10.2 Draft BPC opinion on Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides	
The BPC adopted by consensus the opinion.	**SECR:** to revise the draft opinion in accordance with the discussions in the BPC. **SECR:** to forward the adopted opinion to COM by **19 December 2023** and publish the opinion on the ECHA website.
11. Any other business	
12. Action points and conclusions	

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Part III - List of Attendees

Members (and *alternate members*)

AT	Nina	JOHN
AT	*Reinhild*	*PÜRGY**
BE	Hélène	JARRETY
CH	François	PYTHON
CY	Andreas	HADJIGEORGIOU
CZ	Jan	MIKOLAS
DE	Stefanie	JÄGER
DK	Nina Falk	GREGERSEN
EE	Helen	SULG
EL	Vasileios	VAGIAS
ES	Luisa	GONZÁLEZ MÁRQUEZ
ES	Eduardo	DE LA USADA*
FI	Sanna	KOIVISTO
FR	*Romy*	*COLLET*
FR	Aurélie	CHEZEAU*
HR	Ivana	VRHOVAC FILIPOVC
HU	*Janos*	*BACSO*
IE	Louise	PIERCE
IT	Lucilla	BALDASSARRI
LT	Palmira	HAKAITE
LU	Jeff	ZIGRAND
LV	Julija	BROVKINA
MT	Lothar	MALLIA
NL	Rebekka	LEENDERS
NL	*Lucas*	*KALKERS**
NO	Marit	RANDALL
PL	Helena	RZODECZKO
PT	Teresa	BORGES
RO	Simona	DRAGOIU
SE	Edda	HAHLBECK
SI	Petra	ČEBAŠEK
SK	Denisa	MIKOLASKOVA

Advisors

AT	Dominik	ALTMANN
AT	Lea	BREUL
AT	Christian	KANTNER
BE	Céline	LEROY
CH	Rebekka	BAUMGARTNER
CH	Petra	KUNZ
DE	Nancy	LUDWIG
DE	Anna	LUERICK
DE	Robert	PÖHLER
DE	Viola	WEINHEIMER
ES	Eduardo	DE LA USADA
ES	Maite	HERNÁNDEZ
ES	Myriàm	MARTÍN VALLEJO
ES	Cristina	PORTELA
ES	Elena	RUIZ
NL	Carina	BOS
NL	Nina	COX
NL	Bas	DEKKERS
NL	Sabine	KRUIDHOF
NL	Martine	LANS
NL	Barry	MUIJS
NL	Sander	OTTO
NL	Inge	STORM
NL	Merel	VAN DER PLOEG
PL	Sylwester	HUSZAŁ
SE	Karolin	ASK BJÖRNBERG
SE	Mary	IAKOVIDOU
SK	Alexandra	HORSKA

* Represented the MS on the BPC-49 follow-up day 12 December 2023.

Commission observers

DG SANTE	Marta	CAINZOS
DG SANTE	Ludovic	CHATELIN
DG SANTE	Vincent	DELVAUX
DG SANTE	Sofie	HOFKENS
DG SANTE	Gruhn	LENA
DG SANTE	Konstantinos	TSIAMIS

Accredited Stakeholder Observers

Boris	VAN BERLO
Elodie	CAZELLE
Roman	GYSSELS
Tess	RENAHAN

Applicants

BASF SE
Contect Cleanroom
Diversey Europe Operations
Elanco Animal Health Inc.
Fraunhofer ITEM Biocides
Lubrizol Deutschland GmbH BPR
Microbial Control
Vink Chemicals GmbH & Co. KG

ECHA Staff

Antero	AIRAKSINEN
Lucie	BIELSKA
Janez	BRAJER
Claudio	CARLON
Micaela	DAMSTEN
Anni	HONKA
Helene	JARDIN
Jaana	LAITINEN
Aiga	LATSONE
Eva	MARCON
Lidia	MASLANKIEWICZ
Denis	MOTTET
Gesine	MUELLER
Inka	ORA
Paschalina	PAPADAKI
Chiara	PECORINI
Grethe-Johanna	PLOOMPUU
Mari	RAULIO
Timo	ROCKE
Amaia	RODRIGUEZ-RUIZ
Monica	SAEZ RIBAS
Javier	SANCHEZ SAEZ
Jolanta	STASKO
Katarzyna	SZYMANKIEWICZ
Charlotte	TORDOIR
Andreas	UPHOFF
Sander	VAN DEN LINDEN
Joost	VAN GALEN
Katya	VASILEVA

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-49 & Follow-up day

Agenda Point	Number	Title
2.	BPC-A-49-2023	Draft agenda
4.	BPC-M-48-2023 BPC-M-48-2023	Draft confidential minutes from BPC-48 Draft non-confidential minutes from BPC-48
5.1	-	Administrative issues
6.1	BPC-49-2023-6.1A	BPC Work Programme for active substance approval
	BPC-49-2023-6.1B	BPC Work Programme Union authorisation
	BPC-49-2023-6.1C	outlook for BPC
	BPC-49-2023-6.1D	outlook for BPC and ED assessment
6.2	Presentation	Update on active substance approval
6.3	Presentation	Update on Union Authorisation Processes
6.4	Presentation	Update on article 75(1)(g) mandates
7.1	BPC-49-2023-7.1	Revised working procedure active substances
8.1	BPC-49-2023-8.1	Linguistic review procedure for Union authorisation and major changes applications of a Union Authorisation
8.2	Presentation	
	BPC-49-2023-8.2A	AP 08.02 UA-MIC_Working-procedure_V1-1
	BPC-49-2023-8.2B	AP 08.02 Supporting_document_UA-ADC_v1
	BPC-49-2023-8.2C	AP 08.02 Supporting_document_UA-BBP_UA-BBS_v1

Agenda Point	Number	Substance-PT	eCA	Title
7.2	BPC-49-2023-7.2A1*	Draft BPC opinion on Bronopol for PT 2, 11, 12	ES	Draft BPC opinion PT 2
	BPC-49-2023-7.2A2*			Draft BPC opinion PT 11
	BPC-49-2023-7.2A3*			Draft BPC opinion PT 12
	BPC-49-2023-7.2B			Assessment report
	BPC-49-2023-7.2C*			Open issues
	BPC-49-2023-7.2D			Position paper_ENV-ED
	BPC-49-2023-7.2E			ZIP files

* Rev. versions were distributed prior the follow-up meeting day

	presentation			SECR GNTox dataset analysis
	BPC-49-2023-7.2_room_document			Letter from applicant
8.3	BPC-49-2023-8.3A	Draft BPC opinion on a Union authorisation application for a biocidal product containing Propan-1-ol and Propan-2-ol for PT 1	NL	Draft BPC opinion
	BPC-49-2023-8.3B			SPC
	BPC-49-2023-8.3C			PAR
	BPC-49-2023-8.3D			PAR Conf Annex
	BPC-49-2023-8.3E			Open issues
8.4	BPC-49-2023-8.4A	Draft BPC opinion on a Union authorisation application for a biocidal product containing Propan-2-ol for PT 2	NL	Draft BPC opinion
	BPC-49-2023-8.4B			SPC
	BPC-49-2023-8.4C			PAR
	BPC-49-2023-8.4D			PAR Conf Annex
	BPC-49-2023-8.4E			Open issues
8.5	BPC-49-2023-8.5A	Draft BPC opinion on a Union authorisation application for a biocidal product family containing Active chlorine released from calcium hypochlorite for PT 2, 3	NL	Draft BPC opinion
	BPC-49-2023-8.5B			SPC
	BPC-49-2023-8.5C			PAR
	BPC-49-2023-8.5D			PAR Conf Annex
	BPC-49-2023-8.5E			Open issues
9.1	BPC-49-2023-9.1A	Art 38: Draft BPC opinion on unresolved objections during a mutual recognition procedure for a PT18 biocidal product against poultry red mite, stable fly and darkling beetle	CZ	Draft BPC opinion
	BPC-49-2023-9.1B			Open issues
	BPC-49-2023-9.1C			Conlcusions_WGIII2023
	BPC-49-2023-9.1D			ECHA assessment_WGIII2023
10.1	BPC-49-2023-10.1A	10.1 Draft BPC opinion on Evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)	AT	Draft BPC opinion
	BPC-49-2023-10.1B			Open issues
10.2	BPC-49-2023-10.2A	10.2 Draft BPC opinion on Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides	ECHA	Draft BPC opinion
	BPC-49-2023-10.2B			Open issues
	BPC-49-2023-10.2C			Guidance document
	BPC-49-2023-10.2D			Appendix B
	presentation			Bee guidance presentation

10 November 2023

BPC-A-49-2023_rev1

Draft agenda

49th meeting of the Biocidal Products Committee (BPC) 21-23 November 2023

Meeting is held as hybrid

Meeting room Urho in ECHA/WebEx

Starts on 21 November at 9:30,
ends on 23 November at 13:00
The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-49-2023_rev1

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-48

BPC-M-48-2022

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-49-2023-6.1 A, B, C, D

For information

6.2. Update on active substance approval

For information

6.3. Update on Union Authorisation processes

For information

6.4. Update on article 75(1)(g) mandates

For information

7. – Applications for approval of active substances*

7.1. Revised working procedure active substances

BPC-49-2023-7.1

For agreement

7.2. Draft BPC opinion on bronopol for PT 2, 11, 12

Previous discussion: WG-III-2023

BPC-49-2023-7.2 A, B, C, D, E

For adoption

8. – Union authorisation**

8.1. Linguistic review procedure for Union authorisation and major changes applications of a Union Authorisation

BPC-49-2023-8.1

For agreement

8.2. Working procedure for minor change applications of a Union authorisation and supporting documents for administrative changes and same biocidal products of Union authorisation

BPC-49-2023-8.2 A, B, C

For agreement

8.3. Draft BPC opinion on a Union authorisation application for a biocidal product containing Propan-1-ol and Propan-2-ol for PT 1

Previous discussion: WG-III-2023

BPC-49-2023-8.3 A, B, C, D, E

For adoption

8.4. Draft BPC opinion on a Union authorisation application for a biocidal product containing Propan-2-ol for PT 2

Previous discussion: WG-III-2023

BPC-49-2023-8.4 A, B, C, D, E

For adoption

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

**For 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 E).

8.5. Draft BPC opinion on a Union authorisation application for a biocidal product family containing Active chlorine released from calcium hypochlorite for PT 2, 3

Previous discussion: WG-III-2023

BPC-49-2023-8.5 A, B, C, D, E

For adoption

9. – Article 38 opinion requests

9.1 Draft BPC opinion on Unresolved objections during a mutual recognition procedure for a PT18 biocidal product against poultry red mite, stable fly and darkling beetle

BPC-49-2023-9.1 A, B, C, D

For adoption

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

10.1 Draft BPC opinion on Evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)

Previous discussion: BPC-49

BPC-49-2023-10.1 A, B

For adoption

10.2 Draft BPC opinion on Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides

Previous discussion: ENV WG-II-2023

BPC-49-2023-10.2 A, B C, D

For adoption

11. - Any other business

12. – Action points and conclusions

Provisional time schedule for the

49th meeting of the Biocidal Products Committee (BPC)

Hybrid meeting in Helsinki and in WebEx

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 21 November: (starts at 9:30 EET/08:30 CET, ends at 17:00 EET/16:00 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
Item 6.3	Update on Union Authorisation processes
Item 6.4	Update on article 75(1)(g) mandates
Item 7.1	Revised working procedure active substances
Item 7.2	Draft BPC opinion on bronopol for PT 2, 11, 12

Wednesday 22 November (starts at 9:30 EET/08:30 CET, ends at 17:00 EET/16:00 CET)

Item 8.1	Linguistic review procedure for Union authorisation and major changes applications of a Union Authorisation
Item 8.2	Working procedure for minor change applications of a Union authorisation and supporting documents for administrative changes and same biocidal products of Union authorisation
Item 8.3	Draft BPC opinion on a Union authorisation application for a biocidal product containing Propan-1-ol and Propan-2-ol for PT 1
Item 8.4	Draft BPC opinion on a Union authorisation application for a biocidal product containing Propan-2-ol for PT 2
Item 8.5	Draft BPC opinion on a Union authorisation application for a biocidal product family containing Active chlorine released from calcium hypochlorite for PT 2, 3

Thursday 23 November (starts at 9:30 EET/08:30 CET, ends at 13:00 EET/12:00 CET)

Item 9.1	Draft BPC opinion on unresolved objections during a mutual recognition procedure for a PT18 biocidal product against poultry red mite, stable fly and darkling beetle
Item 10.1	Draft BPC opinion on Evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)
Item 10.2	Draft BPC opinion on Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides
Item 11	Any other business
Item 12	Action points and conclusions

End of meeting

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BPC-M-49-2023

24 November 2023
BPC-A-49-2023_follow-up

Draft agenda

49th meeting of the Biocidal Products Committee (BPC)

Follow-up day in webex

Starts on 12 December at 10:00, ends at 18:00

The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Declarations of potential conflicts of interest to the agenda item

7. – Applications for approval of active substances[1]

7.2. Draft BPC opinion on bronopol for PT 2, 11, 12 – continues from the BPC-49 meeting held on 21-23 November 2023.

Previous discussion: WG-III-2023

BPC-49-2023-7.2 A, B, C, D, E

For adoption

[1] 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).