Final non-confidential minutes of the 48th meeting of the Biocidal Products Committee (BPC)

12-14 September 2023

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
1. Welcome and apologies	
Minutes: The new Chair of the Biocidal Products Committee (BPC), Joost van Galen, welcomed the participants to the 48th BPC meeting which took place as a Webex meeting. The Chair then informed the BPC members of the participation of 28 members, including six alternate members. 34 Advisers and five representatives from an accredited stakeholder organisation (ASO) were present at the meeting. Four observers from the European Commission and three from the European Food Safety Authority attended the meeting. Applicants were invited and present for their specific substances under agenda item 7, biocidal products under agenda item 8, Article 75(1)(g) item under agenda point 9 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-47	
Minutes: The Chair mentioned that all actions from the previous BPC-47 meeting were carried out.	
The revised confidential and non-confidential draft minutes from BPC-47 (BPC-M-47-2023), 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 that the November meeting will be organised as a face-to-face meeting.

The members were informed about their obligations in accordance with the document on the prevention of Conflicts of Interest as agreed in the Management Board.

The members were requested to pay attention to the order of the comments in the open issues table.

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-48 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 November 2023 and asked the involved eCAs to inform the SECR accordingly.

The Chair also informed on the timelines of finalising the opinions 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 **28 September 2023.**

6.2 Update on active substance approval and Union authorisation

Minutes: An update on Union authorisation (UA) and Active substance approval (AS) was given by the SECR. The SECR remarked the inaccuracy of the planning and reminded the members to keep the planning document updated in the Interact Collaboration tool.

i) Workload on AS and UA

SECR presented the current workload of AS and UA dossiers in the opinion forming process and the overview of new submissions for the opinion forming phase by the eCAs coming in.

i) Update from AS processes

SECR informed on:

- the next information session to MSCAs on 26 October 2023;
- the publication on ECHA website of the updated versions of the procedure for post approval data (with applicable day on 9 August) and combined CLH-CAR template;
- an approach change on the SECR-eCA dialogue (step 33 of the AS Working Procedure) applicable from BPC-49 onwards, where SECR will only check the BPC opinion and not the CAR before the commenting round. Comments by SECR will be provided together with the MSCAs during the commenting. This approach affects both AS and UA processes (indicated also below).
- The SECR outlined the changes proposed for an update of the AS Working Procedure, which include the inclusion of renewals, an earlier consultation on CfS whenever possible. The proposal will be distributed among the BPC for comments in written and adoption at BPC-49.

The Commission expressed concerns on the general progress which is still insufficient to conclude the Review Programme. It reminded that Member States must implement the actions agreed at the CA meeting and in the ECHA Active Substance Action Plan. Progress must especially be made on backlog dossiers for which decisions must still be based under the BPD as this is becoming more and more problematic. The Commission remarked that it would be useful to having rolling planning for the on-going year and the next year, considering also that Member States provided forecasts to ECHA.

ii) Update from UA processes

During the meeting the SECR noted that the following documents were published on the ECHA website and thus are applicable from 15 August 2023 - Working Procedure for Union authorisation applications; Post-authorisation conditions for Union authorisations, Working procedure for major changes application of a Union authorisation.

The SECR also invited the applicants and the eCAs to use the quality checklist for the preparation of the summary of product characteristics.

Moreover the members were informed about the change of the approach applicable for Union authorisation and active substance process, i.e., After the working group discussions the eCA provides the updated PAR/CAR, confidential annex of the PAR/CAR, the confidential annex for MSCA only (if applicable), the updated SPC (for UAs) and the draft BPC opinion before the BPC. The SECR was checking and discussing the documents bilaterally with the eCA (before the commenting period was initiated for the MSs and the applicant). From the BPC-49 onwards the SECR will check the documents and provide comments only during the BPC commenting period (together with the MSs and the applicant). The BPC opinion is exceptional – the SECR will check and discuss it bilaterally with the eCA before the commenting is initiated.

The COM noted that they would also welcome information on the status of UAs in the different steps of the procedureas it was presented few years ago. The SECR explained that there are internal discussion ongoing and as soon the draft will be available it will be shared with the COM.

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 29 September and to keep it updated in the future.

6.3 Update on Union Authorisation subprocesses

Minutes: An update was given by the SECR on other Union authorisation (UA) processes: UA changes, UA same biocidal products and UA pre-submissions.

i) Workload

The SECR presented an overview on the number of applications received in 2023 for UA changes and UA pre-submissions and their status. It was noted that an important number of pre-submissions were related to products containing DDAC for PT 2 uses. The number of SBPs linked to UAs that completed opinion forming in 2023 was also presented.

ii) Updates

The SECR noted that the first UA-MIC working procedure was published on the ECHA website on 15 August 2023 and is applicable to all new and on-going UA-MICs. The SECR also noted that opinion forming on UA-MIC had restarted and currently 6 UA-MICs were under commenting.

The COM welcomed this new agenda point to the BPC agenda.

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 29 September cases and to keep it updated in the future.

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
    - 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 year, the other mandate is related to the clarification of endocrine disruption properties for several active substances, for which only work on two active substances is ongoing.
- 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) Mandate on the "Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides"

The SECR presented an overview on the technical guidance development.

The BPC members will be consulted via written consultation once the draft guidance has been revised based on the feedback received from CAs (after CA meeting on 25-29 September). The tentative timeline for BPC consultation is 16-27 October 2023 (to be confirmed after CA meeting).

The technical guidance is expected to be discussed and adopted by the BPC members at BPC-49 meeting, with the aim to finalising the mandate in 2023. Expected publication at the ECHA website is Q1 of 2024.

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 Draft BPC opinion on 2,2-di2,2-dibromo-2-cyanoacetamide (DBNPA) for PT 6

Minutes: 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. DBNPA in PT6 is a review programme substance. In product type 6, DBNPA is intended for use as a short-term preservation of mineral slurries for use in paper production. The preservation and use of the mineral slurry takes place in industrial settings.

The BPC adopted by simple majority the opinion on the approval of the active substance for PT 6.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **02 November**. **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 (DE, SE):** to submit the minority position by **22 September 2023** **SECR:** to forward the adopted opinions to COM by **05 October 2023** and publish them on the ECHA website.

7.2 Draft BPC opinion on Sulfuryl fluoride for PT 8 and 18

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 applicant recognized that at this stage new data cannot be provided to the BPC, but flagged to the members that sulfuryl fluoride is also under evaluation under PPPR and new data has been generated for this process.

The applicant pointed out that the information on the hydrolysis endpoint was accepted in 2010 at the 1st approval of sulfuryl fluoride. During the renewal process the information was re-assessed and the Environment working group concluded that the available data only partly fulfils the information requirement. The information is not necessary for the environmental risk assessment but formally a data gap remains for this core data requirement.

The contribution of sulfuryl fluoride to the global warming potential was noted and will be reflected in the BPC Opinion.

The BPC discussed the impact of the missing data on thionyl fluoride which is considered as relevant impurity for the environment. The BPC concluded that this data gap does not have an impact on the results of the risk assessment for the environment.

COM emphasised that the opinions should clarify that no conclusion on the risk is possible due to the identified data gaps in relation to the ED properties and that these data gaps should be clearly stated in the BPC Opinion.

The BPC adopted by consensus the opinion on the non-renewal of the active substance for PT 08 and PT 18.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **02 November**. **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 **05 October 2023** and publish them on the ECHA website.

8. Union authorisation

8.1 Draft BPC opinion on a Union authorisation application for a biocidal product family containing Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) for PT 6, 11, 12, 13

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.

One BPC member raised the issue whether the uses in the family met the requirement of the BPR that the products in a family should have similar uses. It was agreed that this family would not have to be split according to the previous biocidal product family concept.

One BPC member requested that the RMMs should be aligned between all documents. The rapporteur agreed to check this.

The rapporteur and another member agreed to bilateral agreement after the meeting on amendment of the table on page 301 with regards to spray scenarios.

There was a long discussion on the definition of white water between a member and the rapporteur, in the absence of any other members opposing the wording in the PAR, it was agreed to not amend the PAR. The commenting member made a general statement that this specific eCA has recently been ignoring conclusions from the ENV WG, which results in technical discussions in the BPC. The BPC should not be the forum to discuss such technical issues. The eCA replied that it does not intend to bring

technical matters to the BPC. On the contrary, the discussion whether these identified RMMs are fit for purpose is not within the remit of the working groups and should be brought to the BPC.

An extensive discussion took place on the need for a RMM for the use in PT6 and more specifically for the preservation of plasters. The rapporteur and another member argued that in some cases the use of expert judgement would be acceptable, such as in this case. However, for this case it was not supported by any other member state as the discussion in the WG was conclusive that this use does present a risk for the environment. Therefore, a restriction should be included, treated building materials should only be applied indoors. COM clarified that a restriction on treated articles can only be put in place in the authorisation of a PT6 product if there is a provision in AS approval that allows this (which is not the case for this active substance).

For future cases, if the scenario is considered as too conservative, an early WG discussion should be initiated to amend the scenario.

Following a comment from a member, it was agreed to further explain in the PAR the approach for not proposing RPE for classification EUH071: the semi-quantitative risk assessment in which the external inhalation value is compared to the AEC shows no RPE is necessary for safe use. As the AEC inhalation is based on the same key effect than the classification EUH071, the approach is considered acceptable. However, it was agreed to state that this approach was followed in the absence of applicable guidance and therefore should not be seen as a precedent for future cases.

The naming of the uses should be aligned between all documents. COM requested that the description of uses in all documents (opinion, SPC and PAR) should be clear and meaningful and clearly fit to PT mentioned. Notions like "preservation of 'other'" should be avoided

It was agreed that in the first paragraph of the opinion the table containing the uses should include a column with a conclusion of the risk assessment. COM requested that the table in section 2.1.a (General) should contain information about the uses as supported by the applicant but a table in section 2.e should clarify which uses are finally recommended for authorisation. The BPC could be inspired by previous examples to update its BPC opinion template.The opinion template will be updated accordingly.

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

The BPC adopted by simple 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 **29 September 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. **Member (FI):** to submit the minority position by **22 September 2023** **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **05 October 2023** and publish the opinion on the ECHA website.

8.2 Draft BPC opinion on a Union authorisation application for a biocidal product family containing Hydrogen peroxide for PT 2

Minutes: 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.

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 **29 September 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 **05 October 2023** and publish the opinion on the ECHA website.

8.3 Draft BPC opinion on a Union authorisation application for a biocidal product family containing Hydrogen peroxide for PT 2 and PT 4

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 application of respiratory protection equipment (RPE, APF 40) for professional cleaning staff was discussed. One BPC member raised concerns about the use of RPE (APF 40) in non-health care areas, which may potentially encompass a broad spectrum of areas, including toilets and their routine cleaning. The concern regarding exposure was expressed also in relation to the small molecule of hydrogen peroxide and situations where it might be difficult to ensure sufficient ventilation and to prevent re-entry shortly after use. Further, it was discussed that under PT2 users, the distinction between professional and trained professionals is not made. Based on the arguments provided by the BPC member with reference to a previous case, the rapporteur agreed to amend the PAR and SPC to inform that the product is not intended for use in routine cleaning of toilets.

One BPC member informed about their concerns regarding the use of doses which are significantly above the minimum efficacy doses derived from the efficacy testing, shortly referred to as overdosing. ECHA stated that the issue requires a broader discussion, which cannot be solved at BPC and during a discussion related to a specific product. This topic will be discussed at a more general forum, e.g., in the Competent Authorities (CA) meeting.

One BPC member proposed rewording of a part of the BPC opinion related to coarse spraying (use finally not authorized) and endocrine disruption, which was agreed by rapporteur and finally the BPC.

Following a comment from a member, it was agreed to delete the RMM "Make sure the sleeves of the coverall are taped so there is no space between gloves and coverall" (use 2 of SPC 5) as for now this RMM has not been agreed at WG level for corrosive trigger spray and the efficacy and benefits of this RMM are not demonstrated.

It was also agreed to adjust the RMM for the re-entry in the treated room (replacement of the ventilation of the room by the use a calibrated sensor, air concentration below the relevant reference values before re-entry).

Further an amendment of the BPC opinion (Table in Section 2 with claimed uses) was proposed to also include information on whether the claimed use was/was not proposed for authorization. The rapporteur was informed to also include comments from the Commission when revising the BPC opinion. It was further suggested by a BPC member that comments from the Commission should become part of the open issues table and made available well in advance of the meeting to ensure transparency.

The BPC adopted by simple 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 **29 September 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. **Members (AT, BE):** to submit the minority position by **22 September 2023**

	SECR: to forward the adopted opinion, draft SPC and final PAR to COM by **05 October 2023** and publish the opinion on the ECHA website.
8.4 Draft BPC opinion on a Union authorisation application for a biocidal product family containing L-(+)-lactic acid for PT 2, PT 3 and PT 4	
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 rapporteur explained a technical issue with R4BP that does not allow to specify the SoC ranges per meta SPC in the SPCs XML versions.. SECR noted that the issue should have been resolved in the newest version of the SPC editor expected to be released in November 2023. 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.	
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 **29 September 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 **05 October 2023** and publish the opinion on the ECHA website.
8.5 Note for discussion: the use of expert judgement to define Risk Mitigation Measures	
Minutes: The NL CA was thanked for the note and other BPC members were encouraged to prepare similar notes if they run into more generic issues on which they would like to receive feedback from other member states. It was argued that when using models, it should be possible to use expert judgement when the outcome of the model seems unrealistic. Other member states argued that RMMs should not be applied by default, expert judgement can help here. Enforceability of RMMs should be considered by the BPC, possibly on expert judgment If a model routinely gives an overestimation of the risk, it should be considered to amend the model, via a dedicated discussion/agreement at the concerned WG. We should not come in a situation where we are always overruling the outcome of the model as this would undermine the harmonisation of the risk assessments, especially since this affects applications for union and national procedures. At the same time we could live for a short time with an imperfect model as due to resource issues there is really no possibility to continuously update models. In any case, issues such as this should be discussed in the WGs, for specific cases early WG discussions can be useful. NL will prepare a document to initiate further discussions on this note at the WGs in December 2023, they will approach the WG chairs for this purpose.	
The BPC took note and discussed the note.	**SECR:** to upload the note on Interact. **NL:** to contact the WG chairs and table this item for discussion at the WGs.

9. Article 75(1)(g) opinion requests	
9.1 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 BPC discussed the draft opinion on this request. A BPC member highlighted that the evaluation on whether the derogation criteria under Art.5(2) are met is not only out of the scope of Commission's Art.75(1)(g) mandate to ECHA regarding the availability of alternatives to RP 1:1 and RP 3:2 but is also currently considered as out of BPC remit according to a previously agreed CA document. Two members indicated their support of this view. A BPC member indicated that all the aspects of the potential alternatives could not be investigated due to lack of information, impeding to draw definitive conclusions. They therefore asked to reword the overall conclusions, to be less definitive on the unavailability of suitable alternatives for all PTs and uses. COM instead indicated that they prefer to have clear conclusions to facilitate the decision-making on the approval of the substances. AT agreed to reword the conclusion to be more nuanced. The same BPC member informed about ozone as a potential alternative for PT2 and PT11 currently not included in the assessment. The member will send the information to the eCA for them to take this into account. The same BPC member indicated that in the column "Justification" of the different tables of the opinion the source of information and the reasoning for the justifications are not always clear. In these columns it was suggested to change the term "technically not feasible" by "technical feasibility: questionable" where uncertainty lies. AT responded that regarding technical feasibility, the stability at high pH is generally the issue. AT will consider amending the information in the justification columns where appropriate. COM remarked that the analysis did not include substances which are candidate for substitution or meeting the exclusion criteria as potential alternatives. This approach significantly narrows down the span of potential alternatives, some of them potentially being overall safer. COM therefore suggested, as a general rule, to include such substances in the analyses of alternatives.	
	Rapporteur: to revise the draft opinion for discussion and adoption at BPC-49.
9.2 Request for a BPC opinion on the "Examination of efficacy tier 2 data on specific active substances acting as preservatives (PT 6-13)"	
Minutes: The mandate was introduced by the chair and it was clarified that the eCAs of the original active substance evaluations will act as rapporteur and prepare the opinions. A member state questioned whether the current workload and lack of resources at member state side had been taken in consideration when submitting the mandate. COM clarified that the court has been very clear on what is required for active substance approval and therefore tier 2 data simply needs to be there and needs to be assessed. Workload and lacking resources were therefore not taken into consideration.	
The BPC took note and discussed the mandate and opinion request provided by the SECR.	**SECR:** to upload the mandate on Interact.
10. Any other business	
11. Action points and conclusions	

Part II - Main conclusions and action points

Main conclusions and action points

Agreed at the 48th meeting of BPC

12-14 September 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-47	
The revised confidential and non-confidential draft minutes from BPC-47 (BPC-M-47-2023), 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 that the November meeting will be organised as a face-to-face meeting. The members were informed about their obligations in accordance with the document on the prevention of Conflicts of Interest as agreed in the Management Board. The members were requested to pay attention to the order of the comments in the open issues table.	
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 **28 September 2023.**

6.2 Update on active substance approval and Union authorisation	
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 29 September and to keep it updated in the future.
6.3 Update on Union Authorisation subprocesses	
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 29 September cases and to keep it updated in the future.
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 Draft BPC opinion on 2,2-di2,2-dibromo-2-cyanoacetamide (DBNPA) for PT 6	
The BPC adopted by simple majority the opinion on the approval of the active substance for PT 6.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **02 November**. **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 (DE, SE):** to submit the minority position by **22 September 2023** **SECR:** to forward the adopted opinions to COM by **05 October 2023** and publish them on the ECHA website.
7.2 Draft BPC opinion on Sulfuryl fluoride for PT 8 and 18	
The BPC adopted by consensus the opinion on the non-renewal of the active substance for PT 08 and PT 18.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **02 November**. **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 **05 October 2023** and publish them on the ECHA website.

8. Union authorisation	
8.1 Draft BPC opinion on a Union authorisation application for a biocidal product family containing Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) for PT 6, 11, 12, 13	
The BPC adopted by simple 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 **29 September 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. **Member (FI):** to submit the minority position by **22 September 2022** **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **05 October 2023** and publish the opinion on the ECHA website.
8.2 Draft BPC opinion on a Union authorisation application for a biocidal product family containing Hydrogen peroxide 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 **29 September 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 **05 October 2023** and publish the opinion on the ECHA website.
8.3 Draft BPC opinion on a Union authorisation application for a biocidal product family containing Hydrogen peroxide for PT 2 and PT 4	
The BPC adopted by simple 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 **29 September 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. **Members (AT, BE):** to submit the minority position by **22 September 2022** **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **05 October 2023** and publish the opinion on the ECHA website.

8.4 Draft BPC opinion on a Union authorisation application for a biocidal product family containing L-(+)-lactic acid for PT 2, PT 3 and PT 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 **29 September 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 **05 October 2023** and publish the opinion on the ECHA website.
8.5 Note for discussion: the use of expert judgement to define Risk Mitigation Measures	
The BPC took note and discussed the note.	**SECR:** to upload the note on Interact. **NL:** to contact the WG chairs and table this item for discussion at the WGs.
9. Article 75(1)(g) opinion requests	
9.1 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 discussed the draft opinion on this request.	**Rapporteur:** to revise the draft opinion for discussion and adoption at BPC-49.
9.2 Request for a BPC opinion on the "Examination of efficacy tier 2 data on specific active substances acting as preservatives (PT 6-13)"	
The BPC took note and discussed the mandate and opinion request provided by the SECR.	**SECR:** to upload the mandate on Interact.
10. Any other business	
11. Action points and conclusions	

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Part III - List of Attendees

Members and *alternate members*		
AT	*PÜRGY*	*Reinhild*
BE	JARRETY	Hélène
CH	*GYALPO*	*Tenzing*
CY	HADJIGEORGIOU	Andreas
CZ	MIKOLAS	Jan
DE	JÄGER	Stefanie
DK	GREGERSEN	Nina Falk
EE	SULG	Helen
EL	VAGIAS	Vasileios
ES	GONZÁLEZ	Luisa
FI	KOIVISTO	Sanna
FR	*COLLET*	*Romy*
HR	VRHOVAC FILIPOVIC	Ivana
HU	*HAGYACKIJ-SZABÓ*	*Henrietta*
IE	PIERCE	Louise
IT	BALDASSARRI	Lucilla
LT	HAKAITE	Palmira
LU	*ENSCH*	*Svenja*
LV	*BUKINA*	*Anna*
MT	MALLIA	Lothar
NL	LEENDERS	Rebekka
NO	RANDALL	Marit Espevik
PL	RZODECZKO	Helena
PT	BORGES	Teresa
RO	DRAGOIU	Simona
SE	HAHLBECK	Edda
SI	ČEBAŠEK	Petra
SK	MIKOLASKOVA	Denisa

Advisors		
AT	ALTMANN	Dominik
AT	BREUL	Lea
AT	DERLER	Angelika
AT	HOELZL	Christine
BE	BRASSEUR	Anne
BE	LEROY	Céline
DE	LÜRICK	Anna
DE	PÖHLER	Robert
DE	WEINHEIMER	Viola
DK	JENSEN	Stine
ES	DE LA USADA MOLINERO	Eduardo
ES	RUIZ	Elena
FI	KAUKONIEMI	Sanna
FR	CHÉZEAU	Aurélie
IE	PARR	Mervyn
LV	BROVKINA	Julija
LV	MEZULE	Linda
LV	UŽOMECKAS	Žilvinas
NL	LANS	Martine
NL	MUIJS	Barry
NL	TRINES	Irma
NL	VAN DRIEL	Ruud
NL	WELTEN	Angelique
PL	HUSZAŁ	Sylwester
SE	ASK BJÖRNBERG	Karolin
SE	IAKOVIDOU	Mary
SE	IVANSSON	Milena
SE	LERJEVIK	Ing-Marie
SE	STENSTRÖM	Patrik
SK	DRABOVA KUSIKOVA	Zuzana
SK	HORSKA	Alexandra
SK	LISKOVA	Simona
SK	POLOHOVA	Vladimira
SK	ROMAN	Olga

Commission observers		
DG SANTE	CHATELIN	Ludovic
DG SANTE	DELVAUX	Vincent
DG SANTE	GRUHN	Lena
DG SANTE	TSIAMIS	Konstantinos
EFSA observers		
EFSA	MAGRANS	Jose Oriol
EFSA	PANZAREA	Martina
EFSA	VIANELLO	Giorgia
Accredited Stakeholder Observers		
	AROZAMENA RAMOS	Eduardo
	BARBU	Luminita
	CAZELLE	Elodie
	GYSSELS	Roman
	VAN BERLO	Boris
Applicants		
	ARCHE Consortia	
	Diversey Europe Operations	
	Douglas BLG BVBA (Exponent)	
	Fraunhofer ITEM Biocides	
	ICL Europe	
	Lanxess Deutschland GmbH	
	Microbial Control (Lanxess)	
	TSG Consulting, Veltek Associates Inc.	

ECHA Staff	
AIRAKSINEN	Antero
BIELSKA	Lucie
CARLON	Claudio
DAMSTEN	Micaela
HONKA	Anni
JARDIN	Helene
LAITINEN	Jaana
LATSONE	Aiga
MARCON	Eva M
MASLANKIEWICZ	Lidia
MOTTET	Denis
MUELLER	Gesine
ORA	Inka
PLOOMPUU	Grethe-Johanna
RAULIO	Mari
ROBERTS	Julian
ROCKE	Timo
RODRIGUEZ-RUIZ	Amaia
SAEZ RIBAS	Monica
STASKO	Jolanta
SZANTO	Emese
SZYMANKIEWICZ	Katarzyna
VALKOVICOVA	Eva
VAN GALEN	Joost
VASILEVA	Katya

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-48

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-48 meeting

Agenda Point	Number	Title		
2.	BPC-A-48-2023	Draft agenda		
4.	BPC-M-47-2023 BPC-M-47-2023	Draft confidential minutes from BPC-47 Draft non-confidential minutes from BPC-47		
5.1	-			
6.1	BPC-48-2023-01	BPC Work Programme for active substance approval		
	BPC-48-2023-02	BPC Work Programme Union authorisation		
	BPC-48-2023-03	outlook for BPC		
	BPC-48-2023-04	outlook for BPC and ED assessment		
6.2	Presentation	Update on active substance approval and Union authorisation		
6.3	Presentation	Update on Union Authorisation subprocesses		
6.4	Presentation	Update on article 75(1)(g) mandates		
8.5	BPC-48-2023-12	Note for discussion: the use of expert judgement to define Risk Mitigation Measures		
9.2	BPC-48-2023-13	Request for a BPC opinion on the "Examination of efficacy tier 2 data on specific active substances acting as preservatives (PT 6-13)"		
Agenda Point	**Number**	**Substance-PT**	**eCA**	**Title**
7.1	BPC-48-2023-05A	Draft BPC opinion on 2,2-di2,2-dibromo-2-cyanoacetamide (DBNPA) for PT 6	DK	Draft BPC opinion
	BPC-48-2023-05B			Assessment report
	BPC-48-2023-05C			Open issues
	BPC-48-2023-05D			Supporting documents zip

7.2	BPC-48-2023-06A1	Draft BPC opinion on Sulfuryl fluoride for PT 8 and 18	SE	Draft BPC opinion (PT8)
	BPC-48-2023-06A2			Draft BPC opinion (PT8)
	BPC-48-2023-06B			Assessment report
	BPC-48-2023-06C			Open issues
	BPC-48-2023-06D			Supporting documents zip
	Room docs.			Appl. additional info zip
8.1	BPC-48-2023-07A	Draft BPC opinion on a Union authorisation application for a biocidal product family containing Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) for PT 6, 11, 12, 13	NL	Draft BPC opinion
	BPC-48-2023-07B			SPC
	BPC-48-2023-07C			PAR
	BPC-48-2023-07D			PAR Conf Annex
	BPC-48-2023-07E			Open issues
8.2	BPC-48-2023-08A	Draft BPC opinion on a Union authorisation application for a biocidal product family containing Hydrogen peroxide for PT 2	NL	Draft BPC opinion
	BPC-48-2023-08B			SPC
	BPC-48-2023-08C			PAR
	BPC-48-2023-08D			PAR Conf Annex
	BPC-48-2023-08D1			PAR Conf Annex_MS_ONLY
	BPC-48-2023-08E			Open issues
8.3	BPC-48-2023-09A	Draft BPC opinion on a Union authorisation application for a biocidal product family containing Hydrogen peroxide for PT 2, 4	NL	Draft BPC opinion
	BPC-48-2023-09B			SPC
	BPC-48-2023-09C			PAR
	BPC-48-2023-09D			PAR Conf Annex
	BPC-48-2023-09D1			PAR Conf Annex_MS_ONLY
	BPC-48-2023-09E			Open issues
8.4	BPC-48-2023-10A	Draft BPC opinion on a Union authorisation application for a biocidal product family L-(+)-lactic acid for PT 2, PT 3, PT 4	LV	Draft BPC opinion
	BPC-48-2023-10B			SPC
	BPC-48-2023-10C			PAR
	BPC-48-2023-10D			PAR Conf Annex
	BPC-48-2023-10E			Open issues
9.1	BPC-48-2023-11A	Art 75(1(g): 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-48-2023-11B			Open issues

28 August 2023

BPC-A-48-2023_rev1

Draft agenda

48th meeting of the Biocidal Products Committee (BPC)

12-14 September 2023

Meeting is held virtually in Webex

Starts on 12 September at 10:30,
ends on September 14 at 17:00

The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-48-2023

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-47

BPC-M-47-2022

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-48-2023-01; BPC-48-2023-02; BPC-48-2023-03; BPC-48-2023-04

For information

6.2. Update on active substance approval and Union authorisation

For information

6.3. Update on Union Authorisation subprocesses

For information

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

For information

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

7.1. Draft BPC opinion on 2,2-di2,2-dibromo-2-cyanoacetamide (DBNPA) for PT 6

Previous discussion: WG-II-2023

BPC-48-2023-05 A, B, C, D

For adoption

7.2. Draft BPC opinion on Sulfuryl fluoride for PT 8 and 18

Previous discussion: WG-II-2023

BPC-48-2023-06 A1, A2, B, C, D

For adoption

8. – Union authorisation**

8.1. Draft BPC opinion on a Union authorisation application for a biocidal product family containing Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) for PT 6, 11, 12, 13

Previous discussion: WG-II-2023

BPC-48-2023-07 A, B, C, D, E

For adoption

8.2. Draft BPC opinion on a Union authorisation application for a biocidal product family containing Hydrogen peroxide for PT 2

Previous discussion: WG-II-2023

BPC-48-2023-08 A, B, C, D, E

For adoption

8.3. Draft BPC opinion on a Union authorisation application for a biocidal product family containing containing Hydrogen peroxide for PT 2, 4

Previous discussion: WG-II-2023

BPC-48-2023-09 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).

** 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).

8.4. Draft BPC opinion on a Union authorisation application for a biocidal product family L-(+)-lactic acid for PT 2, PT 3, PT 4

Previous discussion: WG-II-2023

BPC-48-2023-10 A, B, C, D, E

For adoption

8.5. Note for discussion: the use of expert judgement to define Risk Mitigation Measures

BPC-48-2023-12

For discussion

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

9.1 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-43

BPC-48-2023-11 A, B, C

For discussion

9.2 Request for a BPC opinion on the "Examination of efficacy tier 2 data on specific active substances acting as preservatives (PT 6-13)"

BPC-48-2023-13

For information

10. - Any other business

11. – Action points and conclusions

Provisional time schedule for the

48th meeting of the Biocidal Products Committee (BPC)

Virtual meeting 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 12 September (starts at 10:30 EET/09:30 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 and Union authorisation
Item 6.3	Update on Union Authorisation subprocesses
Item 6.4	Update on article 75(1)(g) mandates
Item 7.1	Draft BPC opinion on DBNPA for PT 6

Wednesday 13 September (starts at 10:30 EET/09:30 CET, ends at 17:00 EET/16:00 CET)

Item 7.2	Draft BPC opinion on Sulfuryl fluoride for PT 8 and 18
Item 8.1	Draft BPC opinion on an Union authorisation application for a biocidal product family containing Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) for PT 6, 11, 12, 13
Item 8.3	Draft BPC opinion on an Union authorisation application for a biocidal product family containing containing Hydrogen peroxide for PT 2, 4

Thursday 14 September (starts at 10:30 EET/09:30 CET, ends at 17:00 EET/16:00 CET)

Item 8.2	Draft BPC opinion on an Union authorisation application for a biocidal product family containing Hydrogen peroxide for PT 2
Item 8.4	Draft BPC opinion on an Union authorisation application for a biocidal product family L-(+)-lactic acid for PT 2, PT 3, PT 4
Item 8.5	Note for discussion: the use of expert judgement to define Risk Mitigation Measures
Item 9.1	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 9.2	Request for a BPC opinion on the "Examination of efficacy tier 2 data on specific active substances acting as preservatives (PT 6-13)"
Item 10	Any other business
Item 11	Action points and conclusions

End of meeting

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