Final non-confidential minutes of the 50th meeting of the Biocidal Products Committee (BPC)

26-27 & 29 February 2024

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 50th BPC meeting which took place as a WebEx meeting. 27 BPC members confirmed participation the meeting, including four alternate members (one member was not present at the meeting, although no apologies were received). 38 Advisers and three representatives from an accredited stakeholder organisation (ASO) were present at the meeting (apologies from one ASO were received). Five observers from the European Commission attended the meeting. Applicants were invited and present for their specific substances under agenda item 7 and biocidal products under agenda item 8, where details are provided in the summary record of the discussion for the cases and in Part III of this document.	
2. Agreement of the agenda	
Minutes: The Chair introduced the agenda and indicated the schedule for the three days. The Chair mentioned that agenda items 7.1, 7.4, 8.3 and 8.4 are closed agenda items. The Chair informed the meeting participants that the meeting is recorded for the purpose of the minutes and that the recording will be deleted after the agreement of the minutes. One member suggested to add an additional agenda item on limited evaluation for the renewal of active substances to the agenda. It was included under agenda item 10.4.	
The final draft agenda was agreed.	**SECR:** to add additional agenda point on limited assessment to the agenda. **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-49	

Minutes: The Chair mentioned that all actions from the previous BPC-49 meeting were carried out.	
The revised non-confidential draft minutes from BPC-49 (BPC-M-49-2023), incorporating the comments received, were agreed.	**SECR:** to upload the agreed non-confidential minutes to the ECHA website and Interact.
5. Administrative issues	
Minutes: The Chair informed the meeting that the May meeting will be hybrid, provisional dates being 27-31 May 2024. ECHA apologised for the issues with Interact during BPC-50 commenting and thanked the Member States for their flexibility in handling this issue. The members were informed about the new ECHA strategy and the relevance for their work at the BPC.	
-	**SECR:** to upload the strategy presentation on Interact.
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-50 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 May 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 notify ECHA without delay if they do not have access to the Collaboration in which progress of AS and UA dossiers should be recorded. **Members:** to update the Collaboration on any further changes to the Work Programme (WP) for active substance approval and Union Authorisation by **15 March 2024.** **SECR:** Publish revised version of the AS WP on the BPC website.
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 slowness of the progress and the inaccuracy of the planning provided by Member States and reminded the members to keep the planning document updated in the Interact Collaboration tool, remarking the update of the public version in ECHA website few weeks after the BPC meeting.

The SECR also reported on the implications and actions taken by ECHA to implement the CA agreements from December 2023 CA meeting, and the measures proposed, on the extension of the Review Programme and on substances meeting exclusion. In detail, SECR provided the lessons learnt of the last accordance check performed at the end of January 2024, indicating the uncertainty on the clarity and applicability of some of those measures. Among the actions reported are the efforts to enable the MSCAs to identify and request the ED data timely by providing clear and more targeted information and templates, as well as assistance. For that purpose, a third information session for evaluating CAs is scheduled on 26 March 2024. The session consists in two highly relevant topics: the IUCLID integration; and the ED data request. For the later one, one to one sessions are offered to the eCAs, aiming for a more proactiveness and interaction. BPC agreed to reopen the discussion regarding the BPC-13 "Applicability time of new guidance and guidance-related documents in active substance approval" at a forthcoming BPC.

The BPC took note of the presentation provided by the SECR.	**Members:** to update the Interact Collaboration on the progress of the active substance cases **by 15 March 2024** 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 from 2023. The SECR also updated the BPC on historical data in relation to changes applications of Union authorisations.

The SECR informed the BPC on the status for the post-authorisation data for UAs and proposed for MSs to consider whether the document describing the procedure needs to be reopened to set deadlines for the eCAs in order to ensure that data submitted by the UA holders are processed in the reasonable timelines.

In relation to the planning and general coordination the SECR updated the BPC that 6 MSs provided details of the contact points for UAs (UA CPs). Other UA eCAs were invited to contact the SECR via the UA functional mailbox if they would like to join the UA CPs group.

During the meeting the SECR informed the BPC on the revised and published documents in relation to the quality of the SPC.

In addition, the SECR presented changes to be introduced in the working procedure for major changes applications of a Union authorisation.

Lastly, the SECR updated on the on-going evaluations of minor change applications of Union authorisations (UA-MIC). The SECR particularly highlighted an UA-MIC where the data provided to support the change is the same as the data submitted by the applicant to fulfil the post-authorisation conditions set for the UA. Since the fulfilment of the post-authorisation requirements had not yet been evaluated by the eCA, both the eCA and ECHA are collaborating closely for the evaluation of the data. Thus, the opinion of

the UA-MIC will also include the conclusions on the fulfilment of the post-authorisation conditions.	
The BPC took note of the presentation provided by the SECR.	**Members:** to update the Interact Collaboration on the progress of the union authorisation by **15 March 2024** and to keep it updated in the future. **Members:** to contact UA PC with regards to the idea of written consultation on post-authorisation data **by 15 March 2024.**
6.4 Update on article 75(1)(g) mandates	

Minutes: An update was given by the SECR on the status of the Article 75 (1)(g) mandates.
The SECR presented an overview on the number of Article 75 (1)(g) mandates received for which work is ongoing, and the expected timeline for which their opinions will be discussed at BPC:
• 5 mandates for which work is ongoing
  ○ Discussions and (partial) BPC opinion adoptions expected for 4 of these mandates in 2024.
  ○ Finalisation of 3 mandates expected by the end of 2024.
• 6 expected mandates to arrive.
• 12 finalised mandates in the last 3 years: 4 were finalised in 2023, 3 in 2022 and 5 in 2021.	

The BPC took note of the presentation provided by the SECR.	
6.5 Dissemination of assessment reports (embedded documents)	
Minutes: The SECR presented a harmonised way forward concerning embedded files in disseminated redacted assessment reports (ARs). It was noted that the aim of the harmonisation was the prevention of future access to data (ATD) requests due to ARs containing information that is not accessible. The BPC took note of the presentation provided by the SECR and agreed on way forward. The SECR will update the relevant working procedures accordingly.	
	SECR: to prepare a manual and distribute it for the BPC.
6.6 Minor update of the Active Substance Working Procedure	
Minutes: The BPC took note of the document provided by the SECR and agreed on the updates. Some members indicated their concern to the implementation of the one substance one assessment especially in relation to a harmonisation of the risk assessment. The SECR and the COM explained that the text on one substance one assessment is just a reference to this approach and acknowledged that its implementation is not fully developed yet.	

6.7 Minor updates to the procedures for minor change applications of Union authorisation and revision of the linguistic check of SPC translations of Union authorisation of same biocidal products

Minutes: The BPC took note of the documents provided by the SECR and agreed on the updates.

For the revision of the linguistic check of SPC translations of Union authorisation of same biocidal products, the SECR particularly highlighted that for the final alignment of the Summary of Product Characteristics (SPC) for same biocidal product applications in parallel of a Union authorisation (UA-BBP), ECHA will provide the SPCs of the reference product application to the same biocidal product applicant to include their differences. No remarks on the proposal were made by the participants in the meeting.

7. Applications for approval of active substances

7.1 Draft BPC opinion on the approval of 2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (Prallethrin) for PT 18

Minutes: The Chair welcomed the Applicants for this item. The ASOs were not allowed to be present during the discussion. The rapporteur briefly introduced the case. This is a backlog dossier, for which the applicants submitted separate dossiers in 2006 and a first evaluation was submitted to the Commission in 2012.

All items in the open issue tables were addressed and conclusion reached were recorded in the table.

The BPC adopted by consensus the opinion on the approval of the active substance for PT 18.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **24 April 2024.** **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 **22 March 2024** and publish them on the ECHA website.

7.2 Draft BPC opinion on the approval of Silver zinc zeolite for PT 2, 7, 9

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, explaining that these are backlog dossiers, and the draft opinions were already discussed at BPC-27 and BPC-28. At BPC-28 the opinions were not adopted but it was agreed to include certain restrictions on use categories on treated articles for which the human health risk was not acceptable. Following the BPC-28 discussion, a written consultation took place to collect comments on the exact wording of proposed conditions. Due to the pending endocrine disruptor (ED) assessment the discussion on the conditions was postponed until the ED assessment would be available to the BPC.

For BPC-50 the revised opinions include the ED assessment and the eCA presented a room document on proposed conditions, considering the comments from the written consultation and information received from the Swedish enforcement experts. The Commission suggested to consider for the conditions of treated articles also the latest developments corresponding to more recent BPC opinions. Discussion took place whether restrictions regarding the environmental risk from the use of treated articles outdoors should be phrased and whether at product authorisation refinement would be possible by providing new data which could allow to identify safe use for the environment and make the agreed restrictions obsolete. Commission suggested that the opinion must indicate clearly whether there are risks mitigation measures possible for the outdoor use or not, or if refinement is expected during the product authorisation stage or not, and consider whether the evaluation made was a realistic worst case or over conservative, in order to motivate clearly whether a restrictions on the outdoor use is necessary or not. The eCA clarified that, although risk refinement would be possible at product authorisation, the restriction for outdoor use of treated articles is required in the active substance opinion since it prevents, if at product authorisation no safe use can be identified, that the restriction is limited to treated articles produced within the European Union and imported treated articles produced outside the EU are not restricted. Commission stated that the restriction used should not result in discrimination of treated articles as result of where it has been produced. The possibility to provide new data by any party and requesting amendment of the conditions as stated in Article 7 of the BPR was also clarified. The majority of members agreed to restrict outdoor use for articles treated with silver zinc zeolite in PT 7 and 9. However, one member still has concern as with the decision to restrict outdoor uses, an applicant who wants to apply for product authorisation including treatment of articles for outdoor use, will now first have to apply for amendment of the approval and afterwards for product authorisation. Companies only importing treated articles will then benefit from this Art. 7 application and can place such treated articles on the market without taking any own actions. The applicant argued that the proposed restrictions for products to treat articles are limited to skin contact areas, whereas the migration rate and contact time are also important elements for the exposure assessment but not considered. Further, the reason for the restriction of indirect skin contact via body fluid was not clear for PT 2 and 9. The eCA explained that the contact area is the dominating factor for the risk and the migration and contact time cannot be controlled by enforcement officers. Further the risk for indirect skin contact via body fluid is relevant for treated layers between untreated material from which active substance can migrate into body fluid and further to the skin. One BPC member raised concern regarding the endocrine disruptor properties for humans, arguing that in their opinion no conclusion on the ED properties is possible. All further items in the open issues table were addressed and conclusions reached were recorded in the open issues table.	
The BPC <u>adopted by simple majority</u> the opinion on the approval of the active substance for PTs 2, 7 and 9.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **24 April 2024.** **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 (DK):** to submit the minority positions by **07 March 2024.** **SECR:** to forward the adopted opinions to COM by **22 March 2024** and publish them on the ECHA website.

7.3 Draft BPC opinion on the renewal of Cholecalciferol for PT 14

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.

This is a limited assessment for renewal of approval, for which the applicant submitted a dossier December 2022.

The eCA provided a brief introduction to the case including:

- Opportunity to streamline the renewal process with a limited review
- Specificities regarding the timelines of the limited review
- Data included but not assessed e.g. dermal absorption, thus neither accepted or rejected.

The discussions concerned mainly the nature of the limited assessment and where new information since the previous renewal was acknowledged in the AR. Some possible amendments to wording in AR were discussed to make it clear where no assessment was made. Sweden agreed to make the amendments. Examples included:

- dermal absorption
- ED assessment
- Changes in product composition that have no impact on the decision to approve the AS
- Updates to exposure and risk assessment that do not impact safe use

Possible brief revisions to the Opinion were discussed and agreed upon:

- Clarification that no quantitative risk assessment can be performed since the threshold for endocrine disruptive effects is not known.
- One member questioned the identification as endocrine disruptor in relation to human health emphasising that the current guidance does not adequately reflect how to treat substances with a non-EATS mode-of-action and adequate test guidelines and assessment frameworks are missing. The same member does also question that no safe threshold can be identified considering that cholecalciferol is vitamin D3 and that EFSA has set tolerable upper intake levels for different age groups of up to 100 µg vitamin D equivalents (VDE)/day, as well as defined adequate intakes for all population groups up to 15 µg vitamin D per day to prevent adverse effects on musculoskeletal health. In the present case, adversity can be also be discussed as vitamin D deficiency with manifests in clinical symptoms as rickets in children and osteomalacia in adults. Both are caused by the impaired mineralisation of bone. Furthermore, this member did also not agree with the statement that for other natural occurring substances no exemption was made in relation to the fact that no safe threshold can be set for endocrine disruptors. For bromide (in DPNPA, PT 4 and 6), the BPC concluded that there is safe use due to the essentiality for human health. The same should be valid for cholecalciferol.

- The reference value, e.g., the UL set by EFSA based on human data, is set to protect from elevated serum levels of calcium which is an effect of the endocrine mode of action.
- Removal of the sentence '*If the product is properly used and EU-harmonised risk-mitigation measures are undertaken, the risk of primary and secondary poisoning is reduced'.*

Following discussion, it was agreed that Sweden would elaborate two aspects of the Opinion:

- Consideration of endocrine disrupting properties in the human health risk assessment
- Data gap on skin sensitisation which needs to be addressed at the next renewal.

The Commission remarked that consistency between the RMM for cholecalciferol and AVKs would need to be considered. The Commission also remarked that the Opinion lacked a clear conclusion on possible alternatives of cholecalciferol, especially when it comes to the use for indoor mice. Futhermore, it echoed the remark from one BPC member that, as the rules on the CLP classifications of mixtures containing ED mixtures are now set in the CLP regulation, the BPC should have considered the impact in its recommendations related to the use by the general public. Furthermore, the COM asked to clarify two further issues:

1) why, in comparison with DPNPA, the risks cannot be considered acceptable for cholecalciferol having in mind that it is vitamin D

2) if there are alternatives for mice.

The Commission remarked that if the BPC would decide to adopt the opinion without these points addressed, it would consider referring back the opinion to ECHA.

All items in the open issue tables were addressed and conclusion reached were recorded in the table.

The BPC adopted by consensus the opinion on the renewal of the active substance for PT 14.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **24 April 2024.** **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 **15 March 2024** and publish them on the ECHA website.

7.4 Evaluation of post-approval data submitted for cypermethrin for PT 18

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 discussed and agreed on the updated assessment report.

A draft opinion had been created, however the BPC indicated that no opinion on post-approval data is needed and required by the existing guidance document. Therefore there was no opinion.	
8. Union authorisation	
8.1 Member state experience in rejecting Union Authorisation	
Minutes: A Member State shared their experience as evaluating competent authority in rejecting three applications for Union Authorisation in the validation phase. The BPC took note of the presentation.	
8.2 Draft BPC opinion on the Union Authorisation of a biocidal product family containing L-(+)-lactic acid for PT 3	
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. All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. Upon request the applicant provided further clarification on several points, which were recorded in the open issues table. Afterwards, the members adopted the opinion 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 **15 March 2024.** **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 **22 March 2024** and publish the opinion on the ECHA website.
8.3 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Hydrogen peroxide for PT 2, 4	
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 **15 March 2024.**

	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 **22 March 2024** and publish the opinion on the ECHA website.
8.4 Draft BPC opinion on the Union Authorisation of a biocidal product containing N-cyclopropyl-1,3,5-triazine-2,4,6-triamine (Cyromazine) for PT 18	
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 **15 March 2024.** **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 **22 March 2024** and publish the opinion on the ECHA website.
8.5 e-Consultation: PT designation of surface disinfectant in healthcare areas	
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 discussed the consultation results and BE agreed to prepare a document reflecting the outcome of the discussion.	
	MS BE: to update the document reflecting the outcome and send to SECR. **SECR:** to distribute the updated document to the BPC.

9. Article 75(1)(g) opinion requests	
9.1 Impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant Aspergillus spp.	
Minutes: The SECR explained in the presentation the state of play of the work on the mandate, for which ECHA SECR is acting as Rapporteur. BPC was informed that they will be consulted on certain parts of the mandate in a written consultation. An opinion will be prepared, the whole report will be its Annex. This Article 75(1)g opinion will be scheduled for BPC in November 2024. The BPC took note of the presentation provided by the SECR.	
10. Any other business	
10.1 Reporting on development of in situ guidance	
Minutes: The SECR highlighted that the presentation and the proposal for revision of the CA-July19-Doc.4.1 as submitted for information to BPC 50, were submitted for discussion to the 103rd CA meeting (14-15 March). The SECR explained the changes proposed. The BPC took note of the presentation provided by the SECR.	
10.2 Follow up interviews BPC members in October/November	
Minutes: The chair gave an overview of the outcome of the interviews with the BPC members, focusing on those issues the members are happy with and those issues where members see opportunities for improvement. Several improvements and their status of implementation were presented.	
	SECR: to upload the presentation on Interact.
10.3 Forming a working group for reporting on art 5(2) in the opinion	
Minutes: The chair presented a proposal to form a working group to improve the way art 5(2) is reported on in the opinions for substances meeting the exclusion criteria. The initiative was supported and members were given the opportunity to nominate either themselves or relevant colleagues after the meeting.	
	SECR: to upload the presentation on Interact. **Members:** to inform SECR by email by **15 March 2024** whether they will participate in the working group.
10.4 Limited evaluation	
Minutes: Upon a member request, the BPC discussed on the procedure for the limited-evaluation renewal. The members were concerned of i) the steps and timing of the procedure, including its awareness; ii) the eligibility for limited (or full) evaluation; iii) the format and content of the assessment report (point also indicated relevant for full evaluation renewal); iv) the visibility by the BPC of the updated documents before the meeting; and v) how to deal with the new information with no impact on the assessment. Since it was the first experience with the new process on the renewal with limited evaluation and to provide member further time to provide feedback, the Chair proposed to launch a collaboration.	

	SECR: to create a document listing the items raised during the BPC meeting and open a collaboration. **Members:** provide input **by 15 March 2024** (within 2 weeks after the meeting).
11. Action points and conclusions	

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Part II - Main conclusions and action points

Agreed at the 50th meeting of BPC

26-27 & 29 February 2024

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 add additional agenda point on limited assessment to the agenda. **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-49	
The revised non-confidential draft minutes from BPC-49 (BPC-M-49-2023), incorporating the comments received, were agreed.	**SECR:** to upload the agreed non-confidential minutes to the ECHA website and Interact.
5. Administrative issues	
The **Chair** informed the meeting that the May meeting will be hybrid, provisional dates being 27-31 May 2024. The members were apologised for the issues with Interact during BPC-50 commenting. The members were informed about the new ECHA strategy.	**SECR:** to upload the presentation on Interact.
6. Work programme for BPC	
6.1 BPC Work Programmes for active substance approval, Union authorisation, ED assessment and outlook for BPC	
-	**Members:** to notify ECHA without delay if they do not have access to the Collaboration in which progress of AS and UA dossiers should be recorded. **Members:** to update the Collaboration on any further changes to the Work Programme (WP) for active substance approval and Union Authorisation by **15 March 2024.**

	SECR: Publish revised version of the AS WP on the BPC website.
6.2 Update on active substance approval	
The BPC took note of the presentation provided by the SECR.	**Members:** to update the Interact Collaboration on the progress of the active substance cases by 15 March 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.	**Members:** to update the Interact Collaboration on the progress of the union authorisation by 15 March and to keep it updated in the future. **Members:** to contact Jolanta with regards to the idea of written consultation on post-authorisation data by 15 March.
6.4 Update on article 75(1)(g) mandates	
The BPC took note of the presentation provided by the SECR.	
6.5 Dissemination of assessment reports (embedded documents)	
The BPC took note of the presentation provided by the SECR and agreed on way forward.	**SECR:** to prepare a manual and distribute it for the BPC.
6.6 Minor update of the Active Substance Working Procedure	
The BPC took note of the document provided by the SECR and agreed on the updates.	
6.7 Minor updates to the procedures for minor change applications of Union authorisation and revision of the linguistic check of SPC translations of Union authorisation of same biocidal products	
The BPC took note of the documents provided by the SECR and agreed on the updates.	
7. Applications for approval of active substances	
7.1 Draft BPC opinion on the approval of 2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (Prallethrin) for PT 18	
The BPC adopted by consensus the opinion on the approval of the active substance for PT 18.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **24 April 2024.** **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 **22 March 2024** and publish them on the ECHA website.
7.2 Draft BPC opinion on the approval of Silver zinc zeolite for PT 2, 7, 9	
The BPC adopted by simple majority the opinion on the approval of the active substance for PTs 2, 7 and 9.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **24 April 2024.** **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 (DK):** to submit the minority positions by **07 March 2024.** **SECR:** to forward the adopted opinions to COM by **22 March 2024** and publish them on the ECHA website.
7.3 Draft BPC opinion on the renewal of Cholecalciferol for PT 14	
The BPC adopted by consensus the opinion on the renewal of the active substance for PT 14.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **24 April 2024.** **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 **15 March 2024** and publish them on the ECHA website.
7.4 Evaluation of post-approval data submitted for cypermethrin for PT 18	
The BPC discussed and agreed on the updated assessment report. A draft opinion had been created, however the BPC indicated that no opinion on post-approval data is needed.	
8. Union authorisation	
8.1 Member state experience in rejecting Union Authorisation	
The BPC took note on the presentation provided by the MS SI.	
8.2 Draft BPC opinion on the Union Authorisation of a biocidal product family containing L-(+)-lactic acid for PT 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 **15 March 2024.** **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 **22 March 2024** and publish the opinion on the ECHA website.
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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 **15 March 2024.** **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 **22 March 2024** and publish the opinion on the ECHA website.
8.5 e-Consultation: PT designation of surface disinfectant in healthcare areas	
The BPC discussed the consultation results.	**MS BE:** to update the document reflecting the outcome and send to SECR. **SECR:** to distribute the updated document to the BPC.
9. Article 75(1)(g) opinion requests	
9.1 Impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant Aspergillus spp.	
The BPC took note of the presentation provided by the SECR.	
10. Any other business	

10.1 Reporting on development of in situ guidance	
The BPC took note of the presentation provided by the SECR.	
10.2 Follow up interviews BPC members in October/November	
The BPC discussed on the topic.	**SECR:** to upload the presentation on Interact.
10.3 Forming a working group for reporting on art 5(2) in the opinion	
The BPC discussed on the topic.	**SECR:** to upload the presentation on Interact. **Members:** to inform SECR by email by **15 March 2024** whether they will participate in the working group.
10.4 Limited evaluation	
	SECR: to create a document listing the items raised during the BPC meeting and open a collaboration. **Members:** provide input **by 15 March** (within 2 weeks after the meeting).
11. Action points and conclusions	

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Part III - List of Attendees

BPC members and alternates

AT	Nina	JOHN
BE	Hélène	JARRETY
CH	*Tenzing*	*GYALPO*
CZ	Jan	MIKOLAS
CY	*Maria*	*KOUMI*
DE	Stefanie	JÄGER
DK	Nina Falk	GREGERSEN
EE	Helen	SULG
EL	Vasileios	VAGIAS
ES	Eduardo	DE LA USADA
FI	Sanna	KOIVISTO
FR	Romy	COLLET
HU	*Janos*	*BACSO*
IE	Louise	PIERCE
IT	Lucilla	BALDASSARRI
LT	Palmira	HAKAITE
LU	Jeff	ZIGRAND
LV	Julija	BROVKINA
MT	Lothar	MALLIA
NL	Rebekka	LEENDERS
NO	Marit	RANDALL
PL	*Sylwester*	*HUSZAŁ*
PT	Teresa	BORGES
RO	Simona	DRAGOIU
SE	Edda	HAHLBECK
SI	Petra	ČEBAŠEK
SK	Denisa	MIKOLASKOVA

MS advisers

BE	Anne	LEPAGE
BE	Céline	LEROY
BE	Margot	VAN CAUWENBERGHE
CZ	Tomáš	VACEK
DE	Anna	LUERICK
DE	Jana-Alina	ZUR
DE	Robert	PÖHLER
DE	Susanne	RUDZOK
DE	Viola	WEINHEIMER
DK	Johannes Lørup	BUCH
EL	Akrivi Chara	MOUZAKI PAXINOU
EL	Angeliki	CHARALAMPOUS
EL	Athanasios	GIATROPOULOS
EL	Chris	ANAGNOSTOPOULOS
EL	Dimitra	NIKOLOPOULOU
EL	Fotini	GRIGORIOU
EL	Ioannis	KANDRIS
EL	Ioulia	MOSCHOU
EL	Katerina	BOUTSINI
EL	Niki	ARAPAKI
EL	Panagiotis	GATOS
EL	Thanos	PAPATHANASIS
ES	Elena	RUIZ LÓPEZ
LU	Christina	ROHLES
NL	Angelique	WELTEN
NL	Brigitte	VAN NOORLOOS
NL	Lucas	KALKERS
NL	Marcia	BODERO
NL	Martine	LANS
SE	Karolin	ASK BJÖRNBERG
SE	Nadia	HEILIGERS
SE	Pernilla	BIRGANDER
SE	Tvetomira	PHILIPOVA
SI	Doris	SLOSU
SK	Alexandra	HORSKA
SK	Olga	ROMAN
SK	Ruzena	PILISIOVA
SK	Vladimira	POLOHOVA

Commission observers

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

Accredited Stakeholder Observers

Luminita	BARBU
Roman	GYSSELS
Boris	VAN BERLO

Applicants

Arysta Lifescience Benelux Srl/UPL Deutschlar GmbH

Diversey Europe Operations B.V.

Ecolab Deutschland GmbH

Elanco Animal Health Inc.

ENDURA S.p.A.

Exponent International (Cholecalciferol TF)

Field Fisher Waterhouse LLP

SCC GmbH (on behalf of Novadan ApS)

Sumitomo Chemical (UK) Plc

ECHA Staff

Antero	AIRAKSINEN
Lucie	BIELSKA
Claudio	CARLON
Eva	HAMALAINEN
Anni	HONKA
Helene	JARDIN
Aiga	LATSONE
Eva	MARCON
Jochen	MATTHES
Gesine	MUELLER
Mari	RAULIO
Julian	ROBERTS
Timo	ROCKE
Amaia	RODRIGUEZ-RUIZ
Monica	SAEZ RIBAS
Javier	SANCHEZ SAEZ
Jolanta	STASKO
Emese	SZANTO
Katarzyna	SZYMANKIEWICZ
Charlotte	TORDOIR
Eva	VALKOVICOVA
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-50

Agenda Point	Number	Title
2.	BPC-A-50-2024_rev1	Draft agenda_rev1
4.	BPC-M-49-2023	Draft non-confidential minutes from BPC-49
5.1	presentation	Administrative issues: ECHA strategy statement
6.1	BPC-50-2024-6.1A	BPC Work Programme for active substance approval
	BPC-50-2024-6.1B	BPC Work Programme Union authorisation
	BPC-50-2024-6.1C	outlook for BPC
	BPC-50-2024-6.1D	outlook for BPC and ED assessment
	presentation	Planning BPC-51 and finalising BPC-50
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
6.5	Presentation	Dissemination of assessment reports
6.6	BPC-50-2024-6.6A	Minor update of the Active Substance Working Procedure
6.7	BPC-50-2024-6.7A BPC-50-2024-6.7B	Minor updates to the procedures for minor change applications of Union authorisation and revision of the linguistic check of SPC translations of Union authorisation of same biocidal products
8.1	Presentation	Member state experience in rejecting Union Authorisation
8.5	BPC-50-2024-8.5A BPC-50-2024-8.5B BPC-50-2024-8.5C	e-Consultation: PT designation of surface disinfectant in healthcare areas CH comments EE Comments
9.1	Presentation	Impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant Aspergillus spp.
10.1	BPC-50-2024-10.1 A Presentation	Update on progress: Development of in situ guidance
10.2	presentation	Follow up interviews BPC members in October/November
10.3	presentation	Forming a working group for reporting on art 5(2) in the opinion

Agenda Point	Number	Substance-PT	eCA	Title
7.1	BPC-50-2024-7.1A	Draft BPC opinion on the approval of 2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (Prallethrin) for PT 18	EL	Draft BPC opinion
	BPC-50-2024-7.1B			CAR
	BPC-50-2024-7.1C			Open issues
	BPC-50-2024-7.1D			dCAR_AppendixVI_CONF_app1
	BPC-50-2024-7.1E			dCAR_AppendixVI_CONF_app2
	BPC-50-2024-7.1F			Ref_specs_app1
	BPC-50-2024-7.1G			Ref_specs_app2
	BPC-50-2024-7.1H			Doc_III_after_RCOM
7.2	BPC-50-2024-7.2A1	7.2. Draft BPC opinion on the approval of Silver zinc zeolite for PT 2, 7, 9	SE	Draft BPC opinion PT 2
	BPC-50-2024-7.2A2			Draft BPC opinion PT 7
	BPC-50-2024-7.2A3			Draft BPC opinion PT 9
	BPC-50-2024-7.2B1			CAR_clean
	BPC-50-2024-7.2B2			CAR_w_TC
	BPC-50-2024-7.2C			Open issues
	BPC-50-2024-7.2D			Comments 2019
	BPC-50-2024-7.2E			Additional docs. zip
	BPC-50-2024-7.2room_doc1			Treated articles PT 2
	BPC-50-2024-7.2room_doc2			Treated articles PT 7
	BPC-50-2024-7.2room_doc3			Treated articles PT 9
7.3	BPC-50-2024-7.3A	7.3. Draft BPC opinion on the renewal of Cholecalciferol for PT14	SE	Draft BPC opinion
	BPC-50-2024-7.3B			Risk Assessment report
	BPC-50-2024-7.3C			Open issues
	BPC-50-2024-7.3room_doc1			RCOM
	BPC-50-2024-7.3room_doc2			App_sanitised
7.4	BPC-50-2024-7.4A	7.4. Evaluation of post-approval data submitted for cypermethrin for PT 18	BE	Draft BPC opinion
	BPC-50-2024-7.4B1			DOC_I
	BPC-50-2024-7.4B2			DOC_IIA
	BPC-50-2024-7.4C			Open issues
	BPC-50-2024-7.4D			Conf. study1
	BPC-50-2024-7.4E			Conf. study2

8.2	BPC-50-2024-8.2A	8.2 Draft BPC opinion on the Union Authorisation of a biocidal product family containing L-(+)-lactic acid for PT 3	DK	Draft BPC opinion
	BPC-50-2024-8.2B			SPC
	BPC-50-2024-8.2C			PAR
	BPC-50-2024-8.2D			PAR Conf Annex
	BPC-50-2024-8.2E			Open issues
8.3	BPC-50-2024-8.3A	8.3 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Hydrogen peroxide for PT 2, 4	NL	Draft BPC opinion
	BPC-50-2024-8.3B			SPC
	BPC-50-2024-8.3C1			PAR
	BPC-50-2024-8.3C2			PAR_TC
	BPC-50-2024-8.3D1			PAR Conf Annex
	BPC-50-2024-8.3D2			PAR Conf Annex_TC
	BPC-50-2024-8.3D3			PAR Conf Annex_MS_ONLY
	BPC-50-2024-8.3E			Open issues
8.4	BPC-50-2024-8.4A	8.4 Draft BPC opinion on the Union Authorisation of a biocidal product containing N-cyclopropyl-1,3,5-triazine-2,4,6-triamine (Cyromazine) for PT 18	DE	Draft BPC opinion
	BPC-50-2024-8.4B			SPC
	BPC-50-2024-8.4C			PAR
	BPC-50-2024-8.4D			PAR Conf Annex
	BPC-50-2024-8.4D1			PAR Conf Annex_MS_ONLY
	BPC-50-2024-8.4E			Open issues

29 February 2024
BPC-A-50-2024_final

Final agenda
50th meeting of the Biocidal Products Committee (BPC)
26-27 & 29 February 2024
Meeting is held virtually in Webex

Starts on 26 February at 10:30,
ends on 29 February at 17:00

The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-50-2024_rev1
For agreement

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

4. – Agreement of the minutes and review of actions from BPC-49

BPC-M-49-2023
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-50-2024-6.1 A-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

6.5. Dissemination of assessment reports

For agreement

6.6. Minor update of the Active Substance Working Procedure

BPC-50-2024-6.6 A

For agreement

6.7. Minor updates to the procedures for minor change applications of Union authorisation and revision of the linguistic check of SPC translations of Union authorisation of same biocidal products

BPC-50-2024-6.7 A-B

For agreement

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

7.2. Draft BPC opinion on the approval of 2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (Prallethrin) for PT 18

Previous discussion: WG-IV-2023

BPC-50-2024-7.1 A-H

For adoption

(closed session)

7.3. Draft BPC opinion on the approval of Silver zinc zeolite for PT 2, 7, 9

Previous discussions: TM-II-2013, TM-IV-2013, WG-III-2015, WG-III-2016, WG-V-2016, WG-V-2017, BPC-27, BPC 28, WG-IV-2023

BPC-50-2024-7.2 A1,2&3-E

For adoption

7.4. Draft BPC opinion on the renewal of Cholecalciferol for PT14

BPC-50-2024-7.3 A-C

For adoption

7.5. Evaluation of post-approval data submitted for cypermethrin for PT 18

[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).

Previous discussion: WG-III-2023

BPC-49-2023-7.4 A, B1&2-E

For adoption

(closed session)

8. – Union authorisation**

8.1. Member state experience in rejecting Union Authorisation

For information

8.2. Draft BPC opinion on the Union Authorisation of a biocidal product family containing L-(+)-lactic acid for PT 3

Previous discussion: WG-IV-2023

BPC-50-2024-8.2 A-E

For adoption

8.3. Draft BPC opinion on the Union Authorisation of a biocidal product family containing Hydrogen peroxide for PT 2, 4

Previous discussion: WG-IV-2023

BPC-50-2024-8.3 A, B, C1&2, D1-3, E

For adoption

(closed session)

8.4. Draft BPC opinion on the Union Authorisation of a biocidal product containing N-cyclopropyl-1,3,5-triazine-2,4,6-triamine (Cyromazine) for PT 18

Previous discussion: WG-IV-2023

BPC-50-2024-8.4 A-E

For adoption

(closed session)

8.5. e-Consultation: PT designation of surface disinfectant in healthcare areas

BPC-50-2024-8.5 A-C

For discussion

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

9.1. Impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant Aspergillus spp.

Previous discussion: BPC-46

For information

** For the discussions of the draft BPC opinions at least the following documents will be distributed: a draft BPC opinion (denoted by A), a draft Summary of Product Characteristics (SPC) (denoted by B), a draft product assessment report (PAR) (denoted by C) and a document containing open issues to be discussed for the biocidal product or biocidal product familiy (denoted by E).

10. - Any other business

10.1. Update on progress: Development of in situ guidance

BPC-50-2024-10.1 A

For information

10.2. Follow up interviews BPC members in October/November

For information

10.3. Forming a working group for reporting on art 5(2) in the opinion

For discussion

10.4. Limited evaluation

For discussion

11. – Action points and conclusions

Provisional time schedule for the

50th 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.

Monday 26 February: (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
Item 6.3	Update on Union Authorisation processes
Item 6.4	Update on article 75(1)(g) mandates
Item 6.5	Dissemination of assessment reports
Item 6.6	Minor update of the Active Substance Working Procedure
Item 6.7	Minor updates to the procedures for minor change applications of Union authorisation and revision of the linguistic check of SPC translations of Union authorisation of same biocidal products
Item 7.1	Draft BPC opinion on the approval of 2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (Prallethrin) for PT 18 (closed session)
Item 10.4	Limited evaluation

Tuesday 27 February: (starts at 10:30 EET/09:30 CET, ends at 17:00 EET/16:00 CET)

Item 7.2	Draft BPC opinion on the approval of Silver zinc zeolite for PT 2, 7, 9
Item 7.3	Draft BPC opinion on the renewal of Cholecalciferol for PT 14
Item 7.4	Evaluation of post-approval data submitted for cypermethrin for PT 18 (closed session)
Item 8.1	Member state experience in rejecting Union Authorisation
Item 8.2	Draft BPC opinion on the Union Authorisation of a biocidal product family containing L-(+)-lactic acid for PT 3

Thursday 29 February: (starts at 10:30 EET/09:30 CET, ends at 17:00 EET/16:00 CET)

Item 8.3	Draft BPC opinion on the Union Authorisation of a biocidal product family containing Hydrogen peroxide for PT 2, 4 (closed session)
Item 8.4	Draft BPC opinion on the Union Authorisation of a biocidal product containing N-cyclopropyl-1,3,5-triazine-2,4,6-triamine (Cyromazine) for PT 18 (closed session)

Item 8.5	e-Consultation: PT designation of surface disinfectant in healthcare areas
Item 9.1	Impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant Aspergillus spp.
Item 10.1	Reporting on development of in situ guidance
Item 10.2	Follow up interviews BPC members in October/November
Item 10.3	Forming a working group for reporting on art 5(2) in the opinion
Item 11	Action points and conclusions

End of meeting

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