Final public minutes of the 51st meeting of the Biocidal Products Committee (BPC)

27-31 May 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 51st BPC meeting which took place as a hybrid meeting in ECHA and in WebEx. 29 BPC members confirmed participation the meeting, including five alternate members. Now also Bulgaria had nominated a member for the BPC. 55 Advisers and five representatives from an accredited stakeholder organisation (ASO) were present at the meeting. Five observers from the European Commission and one from EFSA attended the meeting. Applicants were invited and present for their specific substances under agenda item 7 and biocidal products under agenda item 8, Article 75(1)(g) under agenda point 9 and Article 15 (2) item under agenda point 10, where details are provided in the summary record of the discussion for the cases and in Part III of this document.	
2. Agreement of the agenda	
Minutes: The Chair introduced the agenda and indicated the schedule for the five days. The **Chair** mentioned that agenda items 7.3, 8.6 and 8.8 are closed. 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.	
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-50	
Minutes: The Chair mentioned that all actions from the previous BPC-50 meeting were carried out.	
The revised non-confidential and confidential draft minutes from BPC-50 (BPC-M-50-2024), incorporating the comments received, were agreed.	**SECR:** to upload the agreed non-confidential minutes to the ECHA website and Interact and confidential minutes to Interact.
5. Administrative issues	
Minutes: The members were informed on Interact Portal updates - especially the new notifications functionality - by the SECR. The Chair informed the meeting on the following items:	

• BPC members have access to WG minutes via Interact, to be aware of the main issues that were discussed there and are relevant for preparing for the BPC. • September meeting will be virtual, provisional dates being 17-18 September 2024. • WebEx legislate will be likely taken into use for future meetings. • Working Group on Article 5(2) will be organised.	
	SECR: to upload the Interact Portal updates 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-51 the AS WP will be updated again and published on our website. The Chair showed the slide with the foreseen UA and Article 75 (1)(g) opinions for the BPC-52 meeting in September 2024 (no AS cases foreseen) 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 update the Collaboration on any further changes to the Work Programme (WP) for active substance approval and Union Authorisation by **14 June 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 BPC opinion forming. The SECR reminded the members to keep the planning document updated in the Interact Collaboration tool. The SECR reported on the support provided to MSCAs regarding the identification and, when needed, request of missing ED data timely for the June 2024 deadline agreed at the CA meeting December 2023. ECHA recalled that its support to eCAs remains available via 1-to-1 sessions, dossier managers, early working groups of the BPC and the ED expert group. Furthermore, the Agency will request Member States to report on the status concerning the ED assessment for their ongoing assessments to obtain clarity on the progress made. The SECR also Informed on several topics: (i) The ongoing discussions with the Commission and involved MSCAs on the exclusion and derogation criteria for Review Programme substance, where in the absence of a RAC opinion, the BPC has to discuss and conclude on these criteria. (ii) The R4BP 3 update with a new step for the eCA to decide on limited or full evaluation. (iii) The active substances Working Procedure has been updated and the SECR appreciates a reflection on how to best integrate for one substance, one assessment cases contributions from actors outside the BPR area, more explicitly agencies and Member States with parallel ongoing assessments of the same substance under another legislation. The draft had been distributed to the BPC prior to the meeting. The document was discussed at the meeting, and a commenting round was opened.	
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 **14 June 2024** and to keep it updated in the future. **Members:** to provide comments on the updated working procedure by **21 June 2024** (3 weeks).

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 and planned workload of UA dossiers in the opinion forming process. The SECR also updated the BPC on historical data in relation to changes applications of Union authorisations. The SECR also updated on the number of opinions provided by ECHA during Q1 on UA same biocidal products, minor changes and administrative changes. The SECR informed the BPC by considering feedback received after BPC-50 meeting, the procedure for the post-authorisation conditions for Union authorisation will not be reopened. In relation to the planning and general coordination the SECR updated the BPC that 8 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 presented changes proposed for the Working procedure for Union authorisation application, Working procedure for major changes application of a Union authorisation, Working procedure for minor changes application of a Union authorisation. One MS commented a proposal for change of the SPC format and noted that the SPC should be submitted in i6z format, other MSs did not raise objection to this MS proposal. Thus, this will be reflected in the relevant steps of the procedures. There were no comments on other proposed amendments. In addition, the SECR provided a clarification which was agreed with the COM in relation to the submission of the UA major changes applications. • MS who evaluated the initial application for authorisation cannot refuse to be the evaluating MS for the UA-MAC, • The applicant can choose a different MS to evaluate the UA-MAC application, • At the UA-MAC application submission time the written confirmation that the MS agrees to evaluate the UA-MAC is needed only if the application for UA-MAC is submitted to the MS which is different who evaluated the initial application for authorisation. The SECR also noted that recently the SECR published the revised timelines for the opinion forming for major changes applications of a Union Authorisations. Furthermore, the SECR invited the BPC members to take note that active substance source included in the SPC should be (a reference source or technical equivalent source) applicable for all product types included in the biocidal product family/single biocidal product. Lastly, the SECR updated on the on-going evaluations of minor change applications of Union authorisations (UA-MIC). The SECR noted the difficulties in reaching the quorum for UA-MIC BPC opinions. It was noted that the Chair of the BPC will have separate discussions with certain MS to discuss how the procedure can be improved to allow their participation in voting for adopting of UA-MIC opinions.	
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 **14 June 2024** and to keep it updated in the future. **SECR:** to revise the UA, MIC and MAC procedures considering discussions in the BPC meeting and publish on the ECHA website.
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 Article 75 (1)(g) mandates 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: o 6 opinions from 3 different mandates to be discussed and hopefully adopted in this BPC meeting. o Hopefully finalisation an ED related mandate in this BPC meeting with the adoption of a BPC opinion in this meeting. o Discussions and (partial) BPC opinion adoptions expected for 4 of these mandates in 2024.	

- Finalisation of other 2 mandates expected by the end of 2024.
- One mandate, ED properties related, just arrived.
- 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 Harmonisation of approach on active substance renewal

Minutes: The SECR introduced the document "harmonisation approach on active substance renewal" addressing the discussions at BPC-50 and the comments received in the subsequent commenting round, and considering the recent experience on limited-evaluation renewals. ECHA announced to update the corresponding renewal guidance documents accordingly.

The BPC took note of the presentation provided by the SECR and agreed on way forward.	

7. Applications for approval of active substances

7.1. Draft BPC opinion on the renewal of Medetomidine for PT 21

Minutes: The Chair welcomed the Applicants for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case. This is a renewal dossier, PT 21 antifouling, approved in 2016. There are no authorized biocidal products containing medetomidine on the market. The assessment of the renewal dossier involved an evaluation of endocrine disruptive properties. The ED assessment was discussed at the EDEG25 meeting in May 2023 where MSs agreed that considering the overall weight of evidence, the substance meets the ED criteria for human health and no further testing is needed. eCA proposes non-approval of medetomidine as an active substance for PT21.

Medetomidine fulfils the exclusion criteria of Article 5(1) and is considered a candidate for substitution in accordance with four of the conditions in Article 10 (a), (d), (e), and (f). It is vP and T for ENV and ED for ENV NTO. The substance contains a significant proportion of non-active isomers. The AoA identified 26 potential alternative active substances or technologies. SECR proposed not to discuss the majority of items (highlighted in blue) and to accept the conclusions as inserted by SECR, as comments are either editorial or the answer given by the eCA is expected to be accepted by MSs. A member and COM requested several items to be discussed nonetheless; the remaining items proposed to be accepted were accepted. A justification for non-approval was proposed by the eCA, which was accepted after additional suggestions from the COM.

<u>ED discussion</u>

The applicant remarked that, to conclude on ED properties, adversity in an intact organism is necessary and asked if, for Medetomidine, the adversity for both steroidogenesis and the non-EATS modalities were sufficiently investigated. The applicant asked to consider if the adversity been affected by sedation or anaesthesia. The applicant postulated that the adversity was not sufficiently investigated, and further data should be generated. SECR reminded of the EDEG and WG conclusions and asked MSs if they still supported them. The members indicated that the ED properties had already been discussed at the EDEG and WG, after considering the applicant's explanations they still supported the conclusions reached at the EDEG and WG.

<u>Analysis of Alternatives discussion</u>

The Commission requested the inclusion of an analysis on Article 5(2) in the Assessment Report. The eCA proposed additional text, which was subsequently commented on by several members, and the Commission, leading to revisions. The Commission indicated that the other requested revisions were satisfactory. The BPC members supported the revised text.

The applicant was given the opportunity to express his opinion on the AoA. The applicant disagreed with the eCA AoA, particularly with regards to whether other active substances (ASs) which are active against hard and soft fouling, could be considered as alternatives. Thereby also considering the different uses for commercial vessels versus leisure vessels. Several members and the eCA provided further comments, indicating that there are sufficient alternatives, both chemical as well as non-chemical. That

is why it was agreed to conclude that none of the derogation conditions mentioned in Article 5(2) were met. Two member states commented that for meeting Article 5(2)a), it should be crucial whether there is negligible risk from exposure which cannot be the case for antifoulings. However, the COM explained that the availability of alternatives is decisive for all the derogation conditions mentioned in Article 5(2).

The BPC concluded that the analysis of alternatives as prepared by the eCA is fully supported.

Other items

The Commission requested clarification of conclusions on human health (HH) risks excluding endocrine-disrupting (ED) properties. The eCA confirmed that, when not considering ED, no unacceptable risks were identified except for dermal and hand-to-mouth exposure for a young child touching wet paint on a boat surface freshly treated with medetomidine in the representative product. This potential risk to children can be mitigated.

A member asked for a conclusion regarding the environmental scenarios. The BPC agreed not to revise this opinion. A general discussion on the wording in future opinions on risk assessment with regards to endocrine disruption of non target organisms will be held during the BPC 52 meeting.

All other revisions and requests for explanations on different topics were supported by the BPC members.

The BPC adopted by consensus the opinion on the non-renewal of the active substance for PT 21.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **16 July 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 to COM by **28 June 2024** and publish it on the ECHA website.

7.2. Draft BPC opinion on the renewal of Dinotefuran for PT 18

Minutes: The Chair welcomed the Applicants for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case. This is a renewal of approval dossier, PT 18 (Insecticides, acaricides and products to control other arthropods) approved in 2015, re-submission in 2023. Dinotefuran was discussed at the BPC WG in March 2024, following by an environmental ad hoc follow up in April 2024. Dinotefuran meets the criteria from article 10 of the BPR and is therefore considered as a candidate for substitution (vP and T). SECR proposed not to discuss the majority of items (highlighted in blue) and to accept the conclusions as inserted by SECR, as comments are either editorial or the answer given by the eCA is expected to be accepted by MSs. Several MSs and the applicant requested to open several items; the remaining items proposed to be accepted were accepted.

The Applicant asked if a risk assessment for component A (metabolite in water/sediment study under natural sunlight) should be done at the product authorization level. The applicant was advised to contact the eCA who agreed to discuss this question with the applicant after the meeting.

The proposals from the Applicant and MSs for corrections/revisions of the Assessment Report and opinion were discussed and agreed on.

A detailed explanation was provided by eCA why for Dinotefuran there are no alternatives; this is due to the unique mode of action.

Discussion on treated articles

A member raised the issue that for placing treated articles on the market does not require an authorized product. They disagreed that the risk assessment of treated articles can be done at product authorization as at this point it is not possible anymore to place any condition on the use. They expressed the opinion that the placing on the market of treated articles should be regulated at the active substance approval level. They proposed that for renewals where the risk of treated articles was not evaluated, restrictions for treated articles should be implemented and aceptable use categories of treated articles should be specified and listed in the substance approval. They proposed to add the condition in Section 2.3 "Products containing Dinotefuran shall not be used to treat articles". They emphasised that the environmental risks

related to the possible use of treated articles, has not been assessed and reminded that the active substance has vP and T properties. In order to comply with the intention of article 58(2) of the BPR ("relevant product type *and use")*, the member ☐proposed for all substance to come for renewal to consider possible use in treated articles. Another member supported the previously expressed views but proposed to include "Treated articles containing Dinotefuran shall not be placed on the market."

Several members disagreed with the proposal and postulated that restrictions on articles treated with Dinotefuran are not needed. The fact that information on the use in treated articles was missing in the renewal application was not considered sufficient to restrict treated articles. Restrictions on treated articles should only be set if a major concern is identified. However, the vP and T properties of the active substance will not necessarily lead to unacceptable risks for the environment if the active substance is used to treat articles. The majority of the BPC was therefore against adding a sentence on restrictions for treated articles.

The member proposed to add a sentence in the opinion that for dinotefuran treated articles are not expected. This proposal was not agreed, as it would not be in line with previous opinions.

BPC agreed on the warning statement for bees, standard warning phrases for labelling to assure safety of children and pets, and a phrase on when the bittering agent should be added and the deleting the sentence on the minimum level of the efficacy.

A member disagreed with the conclusions made related to the treated articles and informed that a minority opinion will be submitted.

The BPC adopted by simple majority the opinion on the renewal 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 **16 July 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 (SE):** to submit the minority position by **07 June 2024.** **SECR:** to forward the adopted opinion to COM by **28 June 2024** and publish it on the ECHA website.

7.3. Draft BPC opinion on the approval of Polymeric betaine for PT 8

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.

The BPC adopted by consensus the opinion on the approval of the active substance for PT 8.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **16 July 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 to COM by **28 June 2024** and publish it on the ECHA website.

7.4. Draft BPC opinion on the approval of 5-Chloro-2-methyl-2H-isothiazol-3-one (CIT) for PT 6

Minutes: The Chair welcomed the Applicants for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case. The substance was discussed for the second time at the BPC meeting. The first discussion took place at BPC-35 where it was decided to not adopt the opinion due to insufficient data, amongst others, on ED properties in relation to non-target-organisms.

The main discussion concerned the dose concentrations used in the OECD 229 study (FSTRA) to assess whether the active substance may have endocrine disrupting properties towards non-target organisms

(ENV ED). The dose concentrations were too low in comparison to the maximum tolerable concentration required for this test.

The eCA confirmed that a range finding study was performed before starting the FSTRA study. However, the highest dose concentration did not reach the MTC (maximum tolerable concentration). The applicant described that they followed alternative ways in concluding on the doses tested, however these suggestions were not considered acceptable by the environmental working group.

The question arose whether the suggestion developed as an idea to speed up the review programme in the competent authority meeting (CA-meeting) could be used for this new active substance application as well. The suggestion proposes to assess the ENV ED only if the HH ED was positive and to disregard the ENV ED if the HH ED was negative already.

It was agreed that the ideas developed in a CA document are not applicable for this active substance. In the first place because this suggestion remains to be under legal scrutiny, so it could not be applied for any active substance under the BPR. And secondly because the suggestions would apply only for review programme active substances in order to speed up the review programme. New active substances, like CIT, would not fall under this proposal if it were accepted.

The data requirements for the assessment of the HH and the ENV endocrine disrupting properties are core data sets and as such must be fulfilled. The BPC adopted an opinion not to approve the active substance because the core data set is not fulfilled and therefore it was not possible to concluded on the approval conditions specified in Article 4(1) of the BPR.

Some members considered that a non-approval based on insufficient data would be out of proportion and suggested that the applicant be given an additional possibility to provide a valid and conform study. The applicant informed that a new study with higher doses has been contracted, and that the results could be available by 2025.

It was clearly stated that adopting the BPC opinion could not be postponed for a second time, as that would not allow finalising this application of approval of active substance in the timelines foreseen by the BPR. At BPC-35, by exemption, the applicant was given the possibility to submit the lacking study which is now not acceptable. It is not foreseen to request a study a second time during the approval process.

If a new application is submitted, it will need to fulfil all core datasets in agreement with current guidance. In this respect it was mentioned that the genotoxicity endpoint did not follow current guidance and will require new tests for a valid application. A sentence will be added to the opinion, stating that the provided UDS study is not sensitive enough to conclude on the genotoxicity endpoint.

The BPC agreed that information is not sufficient to conclude whether the conditions laid down in Article 4(1) of the BPR are met due to insufficient data on endocrine disruption on non-target organisms and therefore adopted the opinion not to approve the active substance.

The BPC adopted by consensus the opinion on the non-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 **16 July 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 to COM by **28 June 2024** and publish it on the ECHA website.

8. Union authorisation

8.1 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Hydrogen peroxide for PT 4

Minutes: Applicant did not join for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case. Several members raised concerns regarding the references to BPR legal text in the Opinion, noting that in previous cases where non-authorisation was proposed for the whole BPF because of efficacy not being demonstrated, the conclusion for also not meeting Article 19(1)(b)(iii) and Article 19(1)(b)(iv) was not warranted. It was clarified by some member states and the Commission that conditions described in Article 19(1)(b)(iii) and Article 19(1)(b)(iv) can be met

despite minimum efficacious dose not being demonstrated, since the environmental and human health risk assessment is based on the intended application rate as proposed by the applicant. Therefore, the conclusion on meeting Article 19(1)(b)(iii) and Article 19(1)(b)(iv) should relate to the assessment performed for the intended application rate. The BPC Opinion was amended accordingly and presented during the meeting. The BPC adopted the opinion by consensus.	
The BPC adopted by consensus the opinion on the non-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 **18 June 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 **28 June 2024** and publish the opinion on the ECHA website.
8.2 Draft BPC opinion on the Union Authorisation of a biocidal product containing Propan-2-ol for PT2	
Minutes: The Chair welcomed the Applicants for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case. One BPC member requested to remove the risk mitigation measure 'avoid contact to eyes' from the PAR and SPC as they considered the eye contact unlikely in the case of wipes used by professionals and containing quickly evaporating liquid. The rapporteur argued that the RMM relates to product classification as H319 and has been used in similar cases before. For the sake of harmonization with previous cases, the BPC decided not to remove the RMM from PAR/SPC. The Commission shared their view that, in general, unnecessary RMMs should be avoided to keep the RMM sections of SPC focused on the most relevant aspects.	
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 **18 June 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 **28 June 2024** and publish the opinion on the ECHA website.
8.3 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Propan-1-ol;Propan-2-ol for PT 1	
Minutes: The Chair welcomed the Applicants for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case. All points in the table of open issues were addressed and the conclusions reached were recorded in the table of open issues. The BPC members agreed to amend the draft PAR, the draft SPC and the BPC opinion according to the discussion.	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **18 June 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 **28 June 2024** and publish the opinion on the ECHA website.
8.4 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide for PT 19	
Minutes: The Chair welcomed the Applicants for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case. The BPC Chair informed that the applicant sent a letter to BPC Secretariat (on 27 May 2024), noting three areas (shelf file, maximum number of product application per year, environmental exposure assessment scenario) in which their right to be heard was allegedly breached. The BPC chair explained that at the current stage of the procedure the applicant has the opportunity to exercise their right to be heard and asked the applicant to acknowledge whether the issues raised in the letter were all present in the open issue table. The applicant confirmed the presence of all issues in the open issues table (OIT), and therefore, the BPC Chair proceeded with the discussion on the OIT. The applicant was invited to share their concerns for the points raised by him in the open issues table and for other points in the open issues table, if needed. All issues were addressed by the BPC during the discussions on the OIT. One BPC member requested that the justifications collected during the APCP WG and the ad-hoc follow-up meeting for the shelf-life of Meta SPC2 should be added to the PAR and proposed the exact wording, which was accepted by BPC. For the maximum number of applications per year for spot-on applications, which was brought for discussion by the applicant, the rapporteur and their human health expert clarified that this point was raised during the commenting period and marked as closed since an agreement was found during the trilateral discussions. They further explained the technical details behind the applied number of applications per year, which was driven by the need to protect animal health. Two member states shared their concerns regarding the regulatory framework to be applied for products used as repellents against ticks and fleas, where according to their views, such products should be considered as veterinary medicinal products and not biocides. Other member states shared rather opposite views and explained that since no medicinal claim was raised in the present application, the proposed product is a biocidal product. They also lacked clarity as regards to the different approach proposed for products against ticks/fleas compared to those against mosquitoes, because they all are potential vectors of diseases. The Commission asked the concerned BPC members for written feedback, including how they currently approach the borderline cases at national level and the status of the Article 3 request. The BPC strongly recommended the Applicant to remove "antiparasite" from the product and trade names and emphasize the repellent activity instead of the insecticidal activity. The applicant further commented on the shelf-life of 1 year for meta SPC4 and environmental exposure assessment, the rapporteur explained how these topics were addressed and concluded on in the previous steps of the procedure. The BPC concluded that no changes were required.	
The BPC <u>adopted by simple majority</u> 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 **18 June 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. **Members (NL & DE):** to submit the minority position by **07 June 2024.** **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **28 June 2024** and publish the opinion on the ECHA website.

8.5 Draft BPC opinion on the Union Authorisation of a biocidal product containing Glutaral (Glutaraldehyde); Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) for PT 6, 11 and 12	
Minutes: The Chair welcomed the Applicants for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case. The COM and several members questioned the use instruction "consult the manufacturer...", noting that it may be unclear for the user exactly who should be contacted. It was suggested to rephrase the instruction, specifying that the authorisation holder should be contacted, referring to the contact details on the label. The applicant voiced their disagreement with the proposal to remove the trade name "Biosperse" from the products, stemming from the conditions described in CA-June23-Doc.4.9-Final_rev1. The applicant clarified that "Biosperse" is a trademark name that is used globally and refers to a combination of "biocide" and "disperse" without the intention to imply that the products are biological or environmentally-friendly in any way. Moreover, the trade name has been used in other dossiers that have been approved. The applicant invited the BPC to consider that these products are intended for professional use only, so they would not reach the consumer market where the trade name could be misunderstood. It was decided that the trade name will not be removed from the SPC, but the discussion on this matter will take place at the SCBP.	
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 **18 June 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 **28 June 2024** and publish the opinion on the ECHA website.
8.6 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) for PT 4, 11 and 12	
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.	
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 **18 June 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 **28 June 2024** and publish the opinion on the ECHA website.
8.7 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Peracetic acid for PT 2, 3 and 4	
Minutes: The Chair welcomed the Applicants for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case. One member expressed their concerns related to the eCA's evaluation of the coarse spraying application of the corrosive products and/or corrosive dilutions of this application. The member considered that negligeable exposure to these corrosive products/dilutions is not sufficiently demonstrated. However, the majority of the BPC members confirmed their agreement with the conclusion of the human health working group that these uses are acceptable with the risk mitigation measures and personal protective	

equipment proposed for this application.

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

The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **18 June 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 **28 June 2024** and publish the opinion on the ECHA website.

8.8 Evaluation of post-authorisation data submitted for a biocidal product family containing Propan-2-ol for PT 2 & 4

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.

The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **28 June 2024** and publish the opinion on the ECHA website.

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

9.1 Draft BPC opinion on examination of efficacy tier 2 data for RP 1:1 and RP 3:2, PT6 and 13 (4 opinions)

Minutes: The Chair welcomed the Applicants for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case. These 4 opinions were updated in the base of an Article 75 mandate where the Commission requested the re-evaluation of the efficacy at tier 2 data to address whether additional information was necessary, or whether the submitted that was sufficient for tier 2.

The revised opinions presented at this meeting include the conclusions of the BPC-EG-EFF-IV 2023 and BPC-EG-EFF-I 2024 and BPC-EG-EFF-II 2024. In short, the WG concluded that no further data was required, and they specify the intended uses in more details.

Comments:

- A member requested the ED assessment conclusion to be included under overall conclusions of the BPC Conclusions of the evaluation.
- The eCA provided the suggested text at the meeting, and circulated it previously as updated BPC opinion (under the name "rev").
- A member requested the proposed texts with amendments to be circulated beforehand in the open issue table. They reminded that it was agreed not to circulate revised CARs, PARs or opinions ahead of the meeting, but to include all text proposals / amendments in the open issue table.
- A member requested the use of "implemented" or "used" instead of "considered" when addressing the use of RMMs and PPEs: "(…) provided adequate RMM and PPE are implemented" instead of "(…) provided adequate RMM and PPE are considered".

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 opinions.	**Rapporteur:** to revise the draft opinions in accordance with the discussions in the BPC and submit to the SECR by **18 June 2024.**

	SECR: to forward the adopted opinions to COM by **28 June 2024** and publish the opinions on the ECHA website.

9.2 Draft BPC opinion on Questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying (Questions 1-3)

Minutes: Considering the general nature of this opinion, no applicants were invited for this item. The ASOs were allowed to be present during the discussion. The SECR, acting as a rapporteur, briefly introduced the case.

A member, supported by another member, expressed concerns regarding the practical implementation of the principles outlined in this draft opinion, noting that even though some questions have been further addressed under the ongoing revision of the BPR Vol. III guidance, parts B+C, its release would likely be in 2025 or later, and this would be problematic for a number of similar cases that are currently under evaluation. The member also asked for procedural clarification related to the next opinion forming for two of the concerned UA cases (concerning the mandate question #5).

SECR, supported by the Commission, further clarified that:

- the revised guidance will address some of the concerns raised, in particular those related to the local risk assessment. The first draft is under finalisation and is expected to be provided for PEG consultation at the latest by the end of June 2024,
- the Article 75 (1)(g) mandate clearly specifies if the eCA is given an opportunity to ask an applicant to provide additional data to address a specific concern (as done under question 4) or not. Therefore, as no possibility for requesting for additional data has been given under mandate question #5, the eCA's response to it should be based on the information already provided by the applicant within the applications for Union authorisation during their regular opinion development proceedings, in comparison to the principles outlined in this draft opinion (Qs 1-3).

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

The BPC adopted by consensus the opinion.	**Rapporteur:** to revise the draft opinion in accordance with the discussions in the BPC and submit to the SECR by **18 June 2024.** **SECR:** to forward the adopted opinion to COM by **28 June 2024** and publish the opinion on the ECHA website.

10. Article 15(2) opinion requests

10.1 Draft BPC opinion on the review of approval of the active substance zineb

Minutes: The Chair welcomed the Applicants for this item. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the case. Zineb was approved in 2016 for PT21, and this approval will expire in 2025. In 2021, the Commission issued a mandate under Article 15(2) and requested an opinion on whether this AS is considered to have endocrine-disrupting (ED) properties with respect to humans and non-target organisms. The SECR proposed not to discuss the majority of items (highlighted in blue) and to accept the conclusions as inserted by SECR, as comments are either editorial or the answer given by the IE eCA is expected to be accepted by MSs. The BPC members agreed with this proposal, and none of the closed items was reopened.

The notifier shared his view on the current ED assessment. The notifier disagreed with using data from Mancozeb and presented his testing proposal with Zineb.

The notifier disagreed with considering Zineb as an ED in general. They informed that Zineb is used together with copper and therefore it will metabolize differently to Mancozeb. The notifier disagreed also with considering Zineb as an ED specifically for T modality. SECR reminded that this was already discussed by the HH WG and concluded. None of the BPC members wanted to deviate from the HH WG conclusions, therefore the opinion was not amended.

The notifier's testing proposal was not taken into account; SECR explained that the opinion has to be based on the currently available data, and not the data that will be generated in the future. The notifier

informed that the studies are already ongoing and will be submitted at the renewal. SECR explained that the renewal is a different process currently the article 15(2) mandate opinion is discussed. A member asked what will be the follow up steps for Zineb. The Commission explained that the AoA will be done at a later stage. For product authorization ED properties of Zineb have to be taking into account by the national authorities. The Commission also confirmed that Zineb has to be considered as meeting ED criteria in products assessment and the ED properties will be reflected by CLP.	
The BPC adopted by consensus the opinion.	**Rapporteur:** to revise the draft opinion in accordance with the discussions in the BPC and submit to the SECR by **18 June 2024.** **SECR:** to forward the adopted opinion to COM by **28 June 2024** and publish the opinion on the ECHA website.
11. Any other business	
11.1 Clarification about assessment of biocidal products concerning misuse	
Minutes: The SECR presented a document regarding misuse, which was also presented in the CG-61 meeting. The SECR noted that this document was prepared to clarify that misuse should not be considered for product assessment and it does not equal the term "worst case". It was noted that discussion about the terms "worst case" and "foreseeable exposure" shall take place at Working Group level and that guidance documents will be updated in line with the clarification provided with this document.	
The BPC took note of the document provided by the SECR.	
12. Action points and conclusions	
Minutes: Action points and conclusions were agreed, and they have been posted in Interact Meeting.	

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Part II - Main conclusions and action points

Agreed at the 51st meeting of BPC

27-31 May 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 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-50	
The revised non-confidential and confidential draft minutes from BPC-50 (BPC-M-50-2024), incorporating the comments received, were agreed.	**SECR:** to upload the agreed non-confidential minutes to the ECHA website and Interact and confidential minutes to Interact.
5. Administrative issues	
The members were informed on email notifications in Interact (both Collaborations and Meetings). The **Chair** informed the meeting: • that BPC members have access to WG minutes via Interact, to be aware of the main issues that were discussed there and are relevant for preparing for the BPC. • that the September meeting will be virtual, provisional dates being 17-18 September 2024. • regarding the likely use of WebEx legislate for future meetings. • On the organisation of the Working Group on art 5(2).	**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 update the Collaboration on any further changes to the Work Programme (WP) for

	active substance approval and Union Authorisation by **14 June 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 **14 June 2024** and to keep it updated in the future. **Members:** to provide comments on the updated working procedure by **21 June 2024** (3 weeks).
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 **14 June 2024** and to keep it updated in the future. **SECR:** to revise the UA, MIC and MAC procedures considering discussions in the BPC meeting and publish on the ECHA website.
6.4 Update on article 75(1)(g) mandates	
The BPC took note of the presentation provided by the SECR.	
6.5 Harmonisation of approach on active substance renewal	
The BPC took note of the presentation provided by the SECR and agreed on way forward.	
7. Applications for approval of active substances	
7.2. Draft BPC opinion on the renewal of Medetomidine for PT 21	
The BPC adopted by consensus the opinion on the non-renewal of the active substance for PT 21.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **16 July 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 to COM by **28 June 2024** and publish it on the ECHA website.
7.3. Draft BPC opinion on the renewal of Dinotefuran for PT 18	

The BPC adopted by simple majority the opinion on the renewal 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 **16 July 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 (SE):** to submit the minority position by **07 June 2024.** **SECR:** to forward the adopted opinion to COM by **28 June 2024** and publish it on the ECHA website.
7.4. Draft BPC opinion on the approval of Polymeric betaine for PT 8	
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 **16 July 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 to COM by **28 June 2024** and publish it on the ECHA website.
7.5. **Draft BPC opinion on the approval of 5-Chloro-2-methyl-2H-isothiazol-3-one (CIT) for PT 6**	
The BPC adopted by consensus the opinion on the non-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 **16 July 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 to COM by **28 June 2024** and publish it on the ECHA website.
8. Union authorisation	
8.1 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Hydrogen peroxide for PT 4	
The BPC adopted by consensus the opinion on the non-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 **18 June 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 **28 June 2024** and publish the opinion on the ECHA website.

8.2 Draft BPC opinion on the Union Authorisation of a biocidal product containing Propan-2-ol for PT2	
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 **18 June 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 **28 June 2024** and publish the opinion on the ECHA website.
8.3 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Propan-1-ol;Propan-2-ol for PT 1	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **18 June 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 **28 June 2024** and publish the opinion on the ECHA website.
8.4 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide for PT 19	
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 **18 June 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. **Members (NL & DE):** to submit the minority position by **07 June 2024.** **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **28 June 2024** and publish the opinion on the ECHA website.
8.5 Draft BPC opinion on the Union Authorisation of a biocidal product containing Glutaral (Glutaraldehyde); Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) for PT 6, 11 and 12	
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 **18 June 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 **28 June 2024** and publish the opinion on the ECHA website.
8.6 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) for PT 4, 11 and 12	
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 **18 June 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 **28 June 2024** and publish the opinion on the ECHA website.
8.7 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Peracetic acid for PT 2, 3 and 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 **18 June 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 **28 June 2024** and publish the opinion on the ECHA website.
8.8 Evaluation of post-authorisation data submitted for a biocidal product family containing Propan-2-ol for PT 2 & 4	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **28 June 2024** and publish the opinion on the ECHA website.
9. Article 75(1)(g) opinion requests	
9.1 Draft BPC opinion on examination of efficacy tier 2 data for RP 1:1 and RP 3:2, PT6 and 13 (4 opinions)	
The BPC adopted by consensus the opinions.	**Rapporteur:** to revise the draft opinions in accordance with the discussions in the BPC and submit to the SECR by **18 June 2024.**

	SECR: to forward the adopted opinions to COM by **28 June 2024** and publish the opinions on the ECHA website.
9.2 Draft BPC opinion on Questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying (Questions 1-3)	
The BPC adopted by consensus the opinion.	**Rapporteur:** to revise the draft opinion in accordance with the discussions in the BPC and submit to the SECR by **18 June 2024.** **SECR:** to forward the adopted opinion to COM by **28 June 2024** and publish the opinion on the ECHA website.
10. Article 15(2) opinion requests	
10.1 Draft BPC opinion on the review of approval of the active substance zineb	
The BPC adopted by consensus the opinion.	**Rapporteur:** to revise the draft opinion in accordance with the discussions in the BPC and submit to the SECR by **18 June 2024.** **SECR:** to forward the adopted opinion to COM by **28 June 2024** and publish the opinion on the ECHA website.
10. Any other business	
10.1 Clarification about assessment of biocidal products concerning misuse	
The BPC took note of the document provided by the SECR.	
12. Action points and conclusions	

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Part III - List of Attendees

BPC members and alternates

AT	Nina	JOHN
BE	Hélène	JARRETY
BG	Venko	GEORGIEV
CH	François	PYTHON
CY	Andreas	HADJIGEORGIOU
CZ	Jan	MIKOLAS
DE	Stefanie	JÄGER
DK	Nina Falk	GREGERSEN
EE	*Sandra*	*KÄOSAAR*
EL	Vasileios	VAGIAS
ES	Eduardo	DE LA USADA MOLINERO
FI	Sanna	KOIVISTO
FR	*Romy*	*COLLET*
HR	Ivana	VRHOVAC FILIPOVIC
HU	*János*	*BACSÓ*
IE	Louise	PIERCE
IT	Lucilla	BALDASSARRI
LT	Palmira	HAKAITE
LU	*Christina*	*ROHLES*
LV	*Anna*	*BUKINA*
MT	Lothar Paul	MALLIA
NL	Martine	LANS
NO	Marit	RANDALL
PL	Helena	RZODECZKO
PT	Teresa	BORGES
RO	Simona	DRAGOIU
SE	Edda	HAHLBECK
SI	Petra	ČEBAŠEK
SK	Denisa	MIKOLÁŠKOVÁ

MS advisers

AT	Bernhard	WIDHALM
AT	Dominik	ALTMANN
AT	Isabel	KRIEGL
BE	Anne	BRASSEUR
BE	Céline	LEROY
BE	Frédéric	LEFEBVRE
CH	Tenzing	GYALPO
CZ	Tomáš	VACEK
DE	Anna	LUERICK
DE	Florian	MURKE
AT	Bernhard	WIDHALM
DE	Robert	PÖHLER
DE	Viola	WEINHEIMER
EL	Akrivi Chara (Joy)	MOUZAKI PAXINOU
EL	Athanasios	GIATROPOULOS
EL	Evangelia	TZANETOU
EL	Fotini	GRIGORIOU
EL	Ioulia	MOSCHOU
EL	Maritina	LATSOU
EL	Niki	ARAPAKI
EL	Panagiotis	GATOS
EL	Thanos	PAPATHANASIS
EL	Theodosia	FOUNTOULI
ES	Elena	RUIZ
FI	Anna-Maija	HÄMÄLÄINEN
FI	Sari	PENTTINEN
FI	Timo	NIEMINEN
FR	Annabelle	GOUR
FR	Caroline	BOITIER
FR	Fanny	HERARD
FR	Julia	LORI
FR	Léna	NDIAYE
FR	Perrine	CAPDEVILLE
FR	Séléné	VERSTRAET
FR	Xavier	SARDA
IE	Alan	BREEN
IE	Mervyn	PARR
NL	Angelique	WELTEN
NL	Barry	MUIJS
NL	Carina	BOS
NL	Lucas	KALKERS
NL	Marijke	SCHUTTE
NL	Nina	COX
NL	Ruud	VAN DRIEL
NL	Sander	OTTO
NO	Hilde Mariken	ANDERSEN
NO	Marianne	STAVE SEKKENED
SE	Karolin	ASK BJÖRNBERG
SE	Milena	IVANSSON
SE	Tzvetomira	PHILIPOVA
SK	Alexandra	HORSKA
SK	Dávid	DRÁB
SK	Emese	DANADAIOVA
SK	Eva	KARABCIKOVA
SK	Michal	PORUBIAK
SK	Zuzana	DRABOVÁ KUŠÍKOVÁ

Commission observers

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

EFSA observers

EFSA	Alessia	VERANI

Accredited Stakeholder Observers

Luminita	BARBU
Elodie	CAZELLE
Tess	RENAHAN
Boris	VAN BERLO
Aharon	WEISS

Applicants

AGRIA SA
Agrobiothers Laboratoire
CSI-Ireland
Ecolab Deutschland GmbH
Environmental Resources Management Limited
Fraunhofer ITEM Biocides
GAB Consulting GmbH
I-Tech AB
LKC Chem-Regs Ltd.
Rütgers Organics GmbH
Tevan bv
THOR GmbH

ECHA Staff

Antero	AIRAKSINEN
Lucie	BIELSKA
Claudio	CARLON
Micaela	DAMSTEN
Anni	HONKA
Aiga	LATSONE
Eva	MARCON
Lidia	MASLANKIEWICZ
Jochen	MATTHES
Denis	MOTTET
Gesine	MUELLER
Paschalina	PAPADAKI
Grethe-Johanna	PLOOMPUU
Mari	RAULIO
Julian	ROBERTS
Timo	ROCKE
Amaia	RODRIGUEZ-RUIZ
Javier	SANCHEZ SAEZ
Simone	SANTINI
Yasmin	SCHAKIR
Jolanta	STASKO
Emese	SZANTO
Katarzyna	SZYMANKIEWICZ
Charlotte	TORDOIR
Eva	VALKOVICOVA
Sander	VAN DEN LINDEN
Joost	VAN GALEN
Katya	VASILEVA
Francesco	VOLPATTI

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-51

Agenda Point	Number	Title
2.	BPC-A-51-2024_rev1	Draft agenda_rev1
4.	BPC-M-50-2024	Draft non-confidential minutes from BPC-50 Draft confidential minutes from BPC-50
5.1	Presentation	Administrative issues
6.1	BPC-51-2024-6.1A	BPC Work Programme for active substance approval
	BPC-51-2024-6.1B	BPC Work Programme Union authorisation
	BPC-51-2024-6.1C	outlook for BPC
	BPC-51-2024-6.1D	outlook for BPC and ED assessment
	Presentation	Planning BPC-52 and finalising BPC-51
6.2	Presentation BPC-51-2024-6.2	Update on active substance approval Update to the Working Procedure substance approval
6.3	Presentation	Update on Union Authorisation Processes
	BPC-51-2024-6.3A	WP for UA applications
	BPC-51-2024-6.3B	WP for UA MAC applications
	BPC-51-2024-6.3C	WP for UA MIC applications
6.4	Presentation	Update on article 75(1)(g) mandates
6.5	BPC-51-2024-6.5	Harmonisation of approach on active substance renewal
11.1	BPC-51-2024-11.1	Clarification about assessment of biocidal products concerning misuse

Agenda Point	Number	Substance-PT	eCA	Title
7.1	BPC-51-2024-7.1A	7.1 Draft BPC opinion on the approval of Medetomidine for PT 21	NO	Draft BPC opinion
	BPC-51-2024-7.1B			AR
	BPC-51-2024-7.1C			Open issues
	BPC-51-2024-7.1D			AoA annex
	Room doc.			APP PP
	Room doc.			Summary position
7.2	BPC-51-2024-7.2A	7.2. Draft BPC opinion on the approval of Dinotefuran for PT 18	BE	Draft BPC opinion
	BPC-51-2024-7.2B			RAR
	BPC-51-2024-7.2C			Open issues
	BPC-51-2024-7.2D			CONF_RAR_annex
	BPC-51-2024-7.2E			Conf_study_summary

	BPC-51-2024-7.2F			Ref.Specs
	BPC-51-2024-7.2G			SE proposal
7.3	BPC-51-2024-7.3A	7.3. Draft BPC opinion on the approval of Polymeric betaine for PT 8	EL	Draft BPC opinion
	BPC-51-2024-7.3B			CAR
	BPC-51-2024-7.3C			Open issues
	BPC-51-2024-7.3D			Ref_Specs
7.4	BPC-51-2024-7.4A	7.4 Draft BPC opinion on the approval of 5-Chloro-2-methyl-2H-isothiazol-3-one (CIT) for PT 6	FR	Draft BPC opinion
	BPC-51-2024-7.4B			AR
	BPC-51-2024-7.4C			Open issues
	BPC-51-2024-7.4D			CAR
	BPC-51-2024-7.4E			CONF_CAR_doc.
	Room doc.			APP_letter
8.1	BPC-51-2024-8.1A	8.1 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Hydrogen peroxide for PT4	AT	Draft BPC opinion
	~~BPC-51-2024-8.1B~~			~~SPC~~
	BPC-51-2024-8.1C			PAR
	BPC-51-2024-8.1D			PAR Conf Annex
	BPC-51-2024-8.1D1			MS only PAR Conf Annex
	BPC-51-2024-8.1E			Open issues
8.2	BPC-51-2024-8.2A	8.2 Draft BPC opinion on the Union Authorisation of a biocidal product containing Propan-2-ol for PT2	FI	Draft BPC opinion
	BPC-51-2024-8.2B			SPC
	BPC-51-2024-8.2C			PAR
	BPC-51-2024-8.2D			PAR Conf Annex
	BPC-51-2024-8.2E			Open issues
8.3	BPC-51-2024-8.3A	8.3 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Propan-1-ol;Propan-2-ol for PT1	DE	Draft BPC opinion
	BPC-51-2024-8.3B			SPC
	BPC-51-2024-8.3C			PAR
	BPC-51-2024-8.3D			PAR Conf Annex
	BPC-51-2024-8.3E			Open issues
8.4	BPC-51-2024-8.4A	8.4 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide for PT 19	FR	Draft BPC opinion
	BPC-51-2024-8.4B			SPC
	BPC-51-2024-8.4C			PAR
	BPC-51-2024-8.4D			PAR Conf Annex
	BPC-51-2024-8.4E			Open issues
8.5	BPC-51-2024-8.5A	8.5 Draft BPC opinion on the Union Authorisation of a biocidal product containing	FR	Draft BPC opinion
	BPC-51-2024-8.5B			SPC

	BPC-51-2024-8.5C	Glutaral (Glutaraldehyde);Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) for PT 6, 11 and 12		PAR
	BPC-51-2024-8.5D			PAR Conf Annex
	BPC-51-2024-8.5D1			MS only PAR Conf Annex
	BPC-51-2024-8.5E			Open issues
	BPC-51-2024-8.5E			Comparative assessment
8.6	BPC-51-2024-8.6A	8.6 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) for PT 4, 11 and 12	NL	Draft BPC opinion
	BPC-51-2024-8.6B			SPC
	BPC-51-2024-8.6C			PAR
	BPC-51-2024-8.6D			PAR Conf Annex
	BPC-51-2024-8.6E			Open issues
	BPC-51-2024-8.6F			WG_ENV_pos.paper
8.7	BPC-51-2024-8.7A	8.7 Draft BPC opinion on the Union Authorisation of a biocidal product family containing Peracetic acid for PT 2, 3 and 4	NL	Draft BPC opinion
	BPC-51-2024-8.7B			SPC
	BPC-51-2024-8.7C			PAR
	BPC-51-2024-8.7D			PAR Conf Annex
	BPC-51-2024-8.7E			Open issues
8.8	BPC-51-2024-8.8A	8.8 Evaluation of post-authorisation data submitted for Propan-2-ol for PT2 & 4		Draft BPC opinion
	BPC-51-2024-8.8C			PAR
	BPC-51-2024-8.8C			PAR_TC
	BPC-51-2024-8.8E			Open issues
9.1	BPC-51-2024-9.1A1	9.1 Draft BPC opinion on examination of efficacy tier 2 data for RP 1:1 and RP 3:2, PT6 and 13 4 opinions	AT	Draft BPC opinion RP1:1 PT 6
	BPC-51-2024-9.1A2			Draft BPC opinion RP1:1 PT 13
	BPC-51-2024-9.1A3			Draft BPC opinion RP3:2 PT 6
	BPC-51-2024-9.1A4			Draft BPC opinion RP3:2 PT 13
	BPC-51-2024-9.1B1			AR_RP1:1
	BPC-51-2024-9.1B2			AR_RP3:2
	BPC-51-2024-9.1C			Open issues
9.2	BPC-51-2024-9.2A	9.2 Draft BPC opinion on Questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying (Questions 1-3)	ECHA	Draft BPC opinion
	BPC-51-2024-9.2B			Open issues
	BPC-51-2024-9.2C			Annex I_CONF
	BPC-51-2024-9.2D			Annex II_CONF
	BPC-51-2024-9.2E			Appendix_A_to_Annex I_part1
	BPC-51-2024-9.2F			Appendix_A_to_Annex I_part2
	BPC-51-2024-9.2G			Appendix_A_to_Annex I_part3
	BPC-51-2024-9.2H			Appendix_A_to_Annex I_part4
	BPC-51-2024-9.2I			Appendix B to Annex I
	presentation			Intro presentation

10.1	BPC-51-2024-10.1A	10.1 Draft BPC opinion on approval review of zineb	IE	Draft BPC opinion
	BPC-51-2024-10.1B			Open issues
	BPC-51-2024-10.1C			CONF_ann_ED_asssess.
	BPC-51-2024-10.1D			CONF_ann_ED_asssess.eConsult 1
	BPC-51-2024-10.1E			CONF_ann_ED_asssess.eConsult 2

03 June 2024

BPC-A-51-2024_final

Final agenda

51st meeting of the Biocidal Products Committee (BPC)

27-31 May 2024

Meeting is held as hybrid

Meeting room Urho in ECHA/WebEx

Starts on 27 May at 10:00,
ends on 31 May at 13:00

The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-51-2024

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-50

BPC-M-50-2024

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-51-2024-6.1 A, B, C, D

For information

6.2. Update on active substance approval

BPC-51-2024-6.2
For information

6.3. Update on Union Authorisation processes

BPC-51-2024-6.3 A, B, C
For information

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

For information

6.5. Harmonisation of approach on active substance renewal

BPC-51-2024-6.5
For discussion

7. – Applications for approval of active substances*

7.6. Draft BPC opinion on the approval of Medetomidine for PT 21

Previous discussion: WG-I-2024

BPC-51-2024-7.1 A-D
For adoption

7.7. Draft BPC opinion on the approval of Dinotefuran for PT 18

Previous discussion: WG-I-2024

BPC-51-2024-7.2 A-G
For adoption

7.8. Draft BPC opinion on the approval of Polymeric betaine for PT 8 (closed session)

Previous discussion: WG-I-2024

BPC-51-2024-7.3 A-D
For adoption

7.9. **Draft BPC opinion on the approval of 5-Chloro-2-methyl-2H-isothiazol-3-one (CIT) for PT 6**

Previous discussion: WG-I-2024

BPC-51-2024-7.4 A-E
For adoption

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

8. – Union authorisation**

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

Previous discussion: WG-I-2024

BPC-51-2024-8.1 A, C, D, D1,E

For adoption

8.2. Draft BPC opinion on the Union Authorisation of a biocidal product containing Propan-2-ol for PT2

Previous discussion: WG-I-2024

BPC-51-2024-8.2 A-E

For adoption

8.3. Draft BPC opinion on the Union Authorisation of a biocidal product family containing Propan-1-ol;Propan-2-ol for PT 1

Previous discussion: WG-I-2024

BPC-51-2024-8.3 A-E

For adoption

8.4. Draft BPC opinion on the Union Authorisation of a biocidal product family containing Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide for PT 19

Previous discussion: WG-I-2024

BPC-51-2024-8.4 A-E

For adoption

8.5. Draft BPC opinion on the Union Authorisation of a biocidal product containing Glutaral (Glutaraldehyde); Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) for PT 6, 11 and 12

Previous discussion: WG-I-2024

BPC-51-2024-8.5 A-D, D1, E, F

For adoption

8.6. Draft BPC opinion on the Union Authorisation of a biocidal product family containing Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) for PT 4, 11 and 12 (closed session)

Previous discussion: WG-I-2024

BPC-51-2024-8.6 A-F

For adoption

8.7. Draft BPC opinion on the Union Authorisation of a biocidal product family containing Peracetic acid for PT 2, 3 and 4

Previous discussion: WG-I-2024

** 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).

BPC-51-2024-8.7 A-E

For adoption

8.8. Evaluation of post-authorisation data submitted for a biocidal product family containing Propan-2-ol for PT 2 & 4 (closed session)

Previous discussion: BPC-42

BPC-51-2024-8.8 A, C, E

For adoption

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

9.1. Draft BPC opinion on examination of efficacy tier 2 data for RP 1:1 and RP 3:2, PT6 and 13 (4 opinions)

Previous discussions: BPC-43 & EFF WG-I-2024

BPC-51-2024-9.1 A1-4, B1-2, C

For adoption

9.2. Draft BPC opinion on Questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying (Questions 1-3)

Previous discussion: TOX WG-I-2024

BPC-51-2024-9.2 A-I

For adoption

10. – Article 15(2) opinion requests

10.1. Draft BPC opinion on the review of approval of the active substance zineb

Previous discussion: ENV & TOX WG-I-2024

BPC-51-2024-10.1 A-E

For adoption

11. - Any other business

11.1. Clarification about assessment of biocidal products concerning misuse

BPC-51-2024-11.1

For information

12. – Action points and conclusions

Provisional time schedule for the

51st meeting of the Biocidal Products Committee (BPC)

Hybrid meeting in Helsinki and in WebEx

Please note that the time schedule indicated below is provisional and subject to possible change. The schedule is distributed to participants on a preliminary basis. If needed, follow-up discussions may take place on the following days for BPC opinions.

Monday 27 May: (starts at 10:00 EET/09:00 CET, ends at 17:30 EET/16:30 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 6.3	Update on Union Authorisation processes
Item 6.4	Update on article 75(1)(g) mandates
Item 7.4	Draft BPC opinion on the approval of 5-Chloro-2-methyl-2H-isothiazol-3-one (CIT) for PT 6

Tuesday 28 May: (starts at 09:30 EET/08:30 CET, ends at 17:30 EET/16:30 CET)

Item 6.2	Update on active substance approval
Item 6.5	Harmonisation of approach on active substance renewal
Item 7.1	Draft BPC opinion on the approval of Medetomidine for PT 21
Item 7.2	Draft BPC opinion on the approval of Dinotefuran for PT 18

Wednesday 29 May: (starts at 10:00 EET/08:30 CET, ends at 17:30 EET/16:30 CET)

Item 7.3	Draft BPC opinion on the approval of Polymeric betaine for PT 8 (closed session)
Item 9.1	Draft BPC opinion on examination of efficacy tier 2 data for RP 1:1 and RP 3:2, PT6 and 13 (4 opinions)
Item 9.2	Draft BPC opinion on Questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying (Questions 1-3)
Item 10.1	Draft BPC opinion on the review of approval of the active substance zineb
Item 8.1	Draft BPC opinion on the Union Authorisation of a biocidal product family containing Hydrogen peroxide for PT 4
	BPC-51 official dinner

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

Item 8.2	Draft BPC opinion on the Union Authorisation of a biocidal product containing Propan-2-ol for PT2
Item 8.3	Draft BPC opinion on the Union Authorisation of a biocidal product family containing Propan-1-ol;Propan-2-ol for PT 1
Item 8.4	Draft BPC opinion on the Union Authorisation of a biocidal product family containing Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide for PT 19
Item 8.5	Draft BPC opinion on the Union Authorisation of a biocidal product containing Glutaral (Glutaraldehyde); Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1)for PT 6, 11 and 12
Item 8.6	Draft BPC opinion on the Union Authorisation of a biocidal product family containing Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) for PT 4, 11 and 12 (closed session)

Friday 31 May: (starts at 09:30 EET/08:30 CET, ends at 13:00 EET/12:00 CET)

Item 8.7	Draft BPC opinion on the Union Authorisation of a biocidal product family containing Peracetic acid for PT 2, 3 and 4
Item 8.8	Evaluation of post-authorisation data submitted for a biocidal product family containing Propan-2-ol for PT 2 & 4 (closed session)
Item 11.1	Clarification about assessment of biocidal products concerning misuse
Item 12	Action points and conclusions

End of meeting

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