30 September 2022

BPC-M-43-2022_FINAL

Final non-confidential minutes of the 43rd meeting of the Biocidal Products Committee (BPC)

8-9 and 14-16 June

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chair of the Biocidal Products Committee (BPC) welcomed the participants to the 43rd BPC meeting which took place as a virtual meeting via Webex.

The Chair then informed the BPC members of the participation of 26 members, including three alternate members.

32 Advisers (of whom 4 in double role also as an alternate member) and 5 representatives from an accredited stakeholder organisation (ASO) were present at the meeting. Five representatives from the European Commission attended the meeting.

Applicants were invited and present for their specific substances under agenda item 7, biocidal products under agenda item 8, Article 75(1)(g) item under agenda point 9 where details are provided in the summary record of the discussion for the substances and in Part III of the minutes.

2. Agreement of the agenda

The Chair introduced the final draft agenda (BPC-A-43-2022_rev1) and invited any additional items. No additional items were presented and the agenda was adopted. The final version of the agenda will be uploaded to the BPC Interact/Website as part of the meeting minutes.

The Chair informed the meeting participants that the meeting is recorded for the purpose of the minutes and that the recording would be deleted after the agreement of the minutes.

The list of meeting documents and the final version of the agenda are included in Part IV of the minutes.

3. Declarations of potential conflicts of interest to the agenda

The Chair invited BPC members, alternates and advisers to declare any potential conflict of interest in relation to the agreed agenda. None was declared.

4. Agreement of the draft minutes and review of actions arising from BPC-42

The revised draft minutes from BPC-42 (BPC-M-42-2021), incorporating the comments received, were agreed.

The Chair mentioned that all actions from the previous BPC-42 meeting were carried out.

Actions:

- **SECR:** to upload the agreed minutes from BPC-42 to the BPC Interact and to the ECHA website after the meeting.

5. Administrative issues

5.1 Administrative issues

The Chair informed the meeting that the intention is to organise BPC-45 meeting as a hybrid meeting.

ECHA introduced the Interact Security rules for the members.

Actions:

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

6. Work Programme for BPC

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

The Chair informed members that the Work Programme for active substance approval was revised after the last BPC meeting. Members were invited to contact the SECR on possible changes on the revised programme after which an updated version will be published on the ECHA website.

The Chair stated that for 2022 the planned opinions are listed in the “Outlook” document. The total number of adopted opinions will probably be comparable to 2021: the number for UA will increase considerably while for the Review Programme the number will probably be similar. Based on the current status, the total number of expected adopted opinions for 2022 will be 51. For Union authorisation there is a substantial increase compared to 2021: from 15 to 23. For active substance approval there is a decrease in the number of adopted opinions compared to 2021: from 18 to 14 (total) and 14 to 9 (Review Programme). The Chair informed that: i) for process flow 45 the foreseen number is 4; ii) for BPC-45 it is foreseen to adopt an opinion on an Article 38 request; iii) two Article 15(2) opinions are foreseen to be adopted this year: iodine and PVP-iodine for BPC-44 and zineb for BPC-45.

Similarly to previous meetings, the Commission expressed concerns on the general progress which is still insufficient to conclude the review programme by 2024 and reminded that Member States must implement the actions agreed at the CA meeting and in the ECHA Action plan, in particular to deliver the draft assessment reports and to not postpone discussions on their substances from BPC meeting to meeting. Progress must especially be made on backlog reports submitted before 1 September 2013 for which decisions must still be based under BPD principles, which is becoming more and more problematic.

The Chair asked the evaluating Competent Authorities being rapporteur for active substances or Union authorisations scheduled for discussion at the the third BPC meeting of 2022 (BPC-44) to confirm their planning to the SECR as soon as possible.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by **01 July 2022**.

6.2 Update on active substance approval and Union authorisation

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

i) Workload on AS and UA

The SECR presented the current workload of AS and UA dossiers and informed on the planned workload based on the MSs forecast. The SECR pointed out that the CA appointed contact points would need to keep the planning document provided via the Interact Collaboration tool up to date and insert changes in their planning of submissions. SECR noted that due to the low submission of draft CARs in Q4 2021 and Q1 2022 the estimate of BPC opinions on active substance approval had to be reduced.

ii) Update from AS and UA processes

The SECR informed about the organisation of bilateral meetings between the ECHA management and some of the Competent Authorities. In addition, the SECR noted that the development of the new BPC and CG processes based on the agreed approach at CA level for the assessment of new actives substance data submitted during product authorisation is in progress.

SECR also provided recommendations to eCAs on how to request information to the applicant, including the possibility to consider the withdrawal of applications, and reminded eCAs to check whether the necessary data to perform an assessment of ED properties are included in the draft report. A member made a remark about the difficulty to perform the assessment of ED properties within the time frame of the Review Programme due to its step-wise procedure of requesting necessary information. The member questioned whether Member States are obliged to follow this step-wise procedure, considering the need to make progress with the ongoing assessments.

The SECR informed that the recommendation on preparing the SPC for a biocidal product (family) is published on the ECHA website[1]. This document serves as a compilation of agreements made in the Competent Authority, Coordination Group and BPC meetings related to the content of the SPC. The document is published on the SPC Editor web-page under the heading "See also" at https://echa.europa.eu/documents/10162/17242/recommendation_preparing_spc_format_en.pdf/c4a70e46-200a-3217-0631-fd08883521cc?t=1649830082247.

Actions:

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

[1] Title of the document: "Recommendation on preparing a Summary of product Characteristics (SPC) for single biocidal products and biocidal product families."

7. Applications for approval of active substances

7.1 Draft BPC opinion on Formic Acid for PT 2, 3, 4, 5 and 6

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 table.

Discussion took place whether it would be sufficient to demonstrate innate efficacy of formic acid under product type (PT) 6, referring to the need of further efficacy testing with the product at product authorisation. A member argued that in case of treated articles, as relevant here for the use applied for under PT 6 (e.g. use in detergents), the Efficacy Guidance states that '*For treated articles imported into the EU, there is only the active substance approval stage to test efficacy. In this respect, it is particularly important to evaluate and assess use in treated articles at the active substance approval stage.'* (4.5.1, Efficacy Guidance)'.

COM questioned if the guidance has been appropriately followed in regards of sufficient level of efficacy testing noting that Tier 2 testing under realistic conditions is apparently not available. The eCA confirmed that the efficacy assessment for PT 6 has been performed according the Efficacy Guidance in place at the time of the submission of the dossier.

A member argued that a specific condition for treated articles should be included under section 2.3 of the PT 6 opinion to ensure consistency with L(+) lactic acid for PT 6. This is relevant since the (proposed) classification of formic acid is similar to lactic acid in terms of skin corrosion/irritation and eye damage/irritation. The in-use concentration presented in the formic acid AR could be higher in treated articles placed on the market. DE as eCA for lactic acid PT6 informed that an unacceptable risk was identified for L(+) lactic acid whereas this is not the case for formic acid. COM supported the view that in this case a specific condition addressing treated article would not be relevant. However, some reflections on the possibility of a general provision might follow under the decision making process, which may allow to add measures related to treated articles in the SPC at product authorisation. Several members welcomed the possibility of a general provision in the opinion which would allow more flexibility at product authorisation.

The relevance of the default MRL value for formic acid was discussed and it was clarified that this value does apply. The risk of residues in food was not assessed.

All the other issues indicated in the open issues table were discussed and agreed.

The assessment reports for PT 2, 3, 4, 5, and 6 were agreed, and the BPC opinions for PT 2, 3, 4, 5 were adopted by consensus. The BPC opinion for PT 6 was adopted by majority.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 1 July 2022.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **Member's minority (SE):** to submit the minority position for PT 06 by **23 June 2022**

- **SECR:** to forward the adopted opinion to COM by 08 July 2022 and publish it on the ECHA website.

8. Union authorisation

8.1. Revised working procedure for Union authorisation applications and revised working procedure for Linguistic review of SPC translations for Union authorisation

a. Revised working procedure for Union authorisation applications

The revised Working Procedure for Union authorisation applications was presented by the SECR. The working procedure was updated in order to reflect the existing working practice, the use of Interact Collaboration, Interact meetings as well as the use of new RCOM. In addition, the term "peer review" was replaced with the "opinion forming". Several BPC members provided comments: in relation to the deadlines for some steps, including the eCA dossier managers in the communications sent in preparation of the Working Group discussion table and BPC open issue table; closing of the points during the disagreement in closing steps etc.. The BPC members agreed with the SECR proposal to update the Annex of the Working Procedure. The SECR will revise the working procedure based on the discussion at the BPC meeting and will publish it on the ECHA website.

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

The SECR presented a proposal in relation to the applicant`s involvement during the opinion forming process. A proposal was made with the aim to simplify the process in order to cope with the high number of Union authorisation applications entering the opinion forming process. Two scenarios were proposed for the BPC members consideration. In general BPC members expressed a support for the proposal however, some of the MSs supported Scenario 1 and some Scenario 2. A member proposed to keep the current practice but enforce that the applicant is only allowed to indicate which of their comments made during the 30 days commenting period before the start of the peer review, were not taken over by the eCA . COM invited ECHA and the BPC to reflect on the consistency, and possible need, to revise the procedures related to the active substance approval process as necessary. In order to collect further comments, the SECR will open a commenting period for ASOs and the members.

c. Revised working procedure for linguistic review of SPC translations for Union authorisation

The SECR presented the revised procedure for linguistic review of the translations of the SPC for Union authorisation applications. The SECR informed that the procedure is updated in relation to the necessity to provide the SPC translations in Irish. The part in relation to same biocidal product applications was removed and is provided separately. During the discussion, the SECR reminded MSs to keep the applicant informed on the progress of the review of the SPC translations. The SECR will revise the document further based on the discussion during the BPC meeting and will publish it on ECHA website.

d. Working procedure for linguistic review of SPC translations for same biocidal products applications for Union authorisation

The SECR presented the draft procedure for linguistic review of the translations of the SPC for Union same biocidal product applications. Two situations were presented in the document:

- one where the applicant of the SBP is the same as the applicant of the reference UA and for which a linguistic review is considered not needed because this is already done for the reference UA application;
- another one where the applicant of the SBP is different from the applicant of the reference UA and for which a linguistic review is needed.

A BPC member commented that the SPC of a SBP application should be identical to the SPC of the related reference product, except for those sections affected by administrative changes. Several BPC members expressed concerns about the approach suggested. Therefore, SECR will consider the comments provided and will come back in a next meeting with a revised proposal.

8.2 Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from chlorine PT 2, 5

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

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

Procedural clarification was sought on the product classification in hazard classes not included in an Annex VI entry of the CLP Regulation for the active substance.

The SECR clarified that in such a case, based on available information:

- either a CLH proposal for modification of the CLH entry for the active substance could be made by the eCA that evaluated the active substance or any other MSCA, or
- although the CLH of the active substance for the listed there hazard classes are binding and should be followed, the product may be further self-classified for hazard classes, not mentioned in the Annex VI entry, where considered appropriate and justified.

A member noted that although he would refrain from filing a minority position in this Union authorisation case, he holds the same view, as expressed in their minority position provided during the opinion adoption at BPC-39 on the Union authorisation application for a biocidal product containing active chlorine released from chlorine PT 2,5.

The opinion was adopted by majority. A member disagreed pointing out that the current SPC does not match the German national laws and specifications. Thus, Germany intends to send a derogation request to Commission according to Article 44(5). The Commission requested the German authorities to provide as soon as possible their justifications for the derogations that should demonstrate why specific conditions should apply to Germany. An SPC in English that includes the changes requested by Germany is required.

Actions:

- **Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **1 July 2022.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **Member's minority (DE):** to submit the minority position by **23 June 2022**
- **SECR:** to forward the adopted opinion, minority posision, draft SPC and final PAR to COM by **8 July 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **16 August 2022**.

8.3 Draft BPC opinion on an Union authorisation application for a biocidal product containing calcium dihydroxide / calcium hydroxide / caustic lime / hydrated lime / slaked lime PT 2, 3

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

The rapporteur briefly introduced both dossiers containing lime based active substance because they are very similar. The rapporteur proposed that the product containing hydrated lime cannot be authorised for the disinfection of animal bedding because the efficacy was not demonstrated for this use. Both biocidal products can be authorised for the other uses claimed according to the restrictions and RMMs reported in the PAR and SPC.

A discussion took place related to the issue of the possibility of having – as proposed by the eCA - 2 formulation types in a single biocidal product application. It was the first time this occurred in the authorisation of biocidal products. First of all it was argued that the preferred approach in such cases would be an application of a biocidal product family (with different meta SPCs for the different formulation types). It was discussed whether in the present case this could however still be accepted as there was only a dilution step with water before use. As the biocidal product placed on the market is the same for both formulation types and the human health and environmental risks and efficacy and physical hazard aspects were covered it was concluded that in this exceptional case this could be accepted. A BPC member proposed to have a more generic formulation type covering both the dustable and the wettable powder. This was endorsed by the members.

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The opinion was adopted by majority. One BPC member indicated that they would submit a minority opinion due to the fact that they do not agree with the final conclusion considering only the qualitative assessments made for use 3 (disinfection of indoor floor sufaces of animal accommodations and transportation), use 4 (disinfection of animal bedding materials) and the scenario "disposal of small bags" and ignore the unacceptable risks identified in the quantitative assessments. This in spite of the fact that the results of the qualitative assessment were agreed by the majority of the Human Health Working Group. The BPC members supporting the conclusions of the Working Group.

Actions:

- **Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **1 July 2022.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **Member (DE):** to submit the minority position by **23 June 2022.**
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **29 July 2022**.

8.4 Draft BPC opinion on an Union authorisation application for a biocidal product containing calcium oxide / lime / burnt lime / quicklime PT 2, 3

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

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The opinion was adopted by by majority. As for the previous biocidal product, the same BPC member indicated that they will submit a minority opinion due to the fact that they do not agree with the final conclusion considering only the qualitative assessment for the uses and scenario indicated under agenda item 8.3 made ignoring the unacceptable risks identified in the quantitative assessment.

Actions:

- **Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **1 July 2022.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **Member (DE):** to submit the minority position by **23 June 2022.**
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **29 July 2022**.

8.5 Draft BPC opinion on an Union authorisation application for a biocidal product family containing Peracetic acid PT 2, 3, 4

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

Only a limited number of comments were made. All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **1 July 2022.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **29 July 2022**.

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

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

The family consists of one meta SPC with one use: toilet disinfection by manual application. Non-authorisation of the biocidal product family was proposed by the eCA due to unacceptable risks for the environment and for non-professional and professional users as well as missing storage stability data. The proposal not to authorise the use for professional users was challenged as the risk could be reduced by introducing strict risk management measures (RMM), e.g. wearing a gas mask during brushing and flushing and by introducing a 60 minutes ventilation time prior to re-entry of general public into the toilet facilities after brushing and flushing. However, these RMMs were considered as not feasible by the majority of the members.

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

Actions:

- **Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **1 July 2022.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **29 July 2022**.

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

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

SECR informed about the eCA's request for renumbering the metaSPCs in this application and supported this initiative to achieve more clarity. The BPC agreed.

The main item of discussion was regarding the status of BEIPUR ANP as part of the biocidal product. It was concluded that based on efficacy data and instructions for use, BEIPUR ANP must be considered an integral part of the biocidal product for the use in laundry

disinfection. Also the applicant confirmed that efficacy is substantially modulated by the presence of BEIPUR ANP. Following from this conclusion, it was agreed that assessment including the contribution of BEIPUR ANP was required as done by the eCA. The eCA clarified on request that BEIPUR did not trigger any concern for the environmental assessment and agreed to address this in the PAR in more detail. As BEIPUR ANP was considered integral part of the biocidal product, it was also discussed how it should be mentioned in the SPC, concluding that the composition will be only reported in the confidential annex to the PAR while the instructions for use will be mentioned explicitly for BEIPUR ANP in the SPC.

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

Actions:

- **Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **1 July 2022.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur and request submission of a new IUCLID dossier from the applicant according to open issue #8.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **16 August 2022**.

8.8 Draft BPC opinion on an Union authorisation application for a biocidal product family containing L-(+)-lactic acid PT 3, 4

The Chair welcomed the applicant. The ASOs were not allowed to be present during the discussion. The rapporteur briefly introduced the dossier.

Only a limited number of comments were made. All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **1 July 2022.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **16 August 2022**.

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

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

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The opinion was adopted by majority. A member indicated that they will submit a minority opinion due to the virucidal claim for some of the uses, which are proposed for authorisation only against enveloped viruses in PT 4. This approach was accepted during a discussion in the Efficacy Working Group as explained by the SECR.

Actions:

- **Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **1 July 2022.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **Member (DK):** to submit the minority position by **23 June 2022**.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **29 July 2022**.

8.10 Draft BPC opinion on an Union authorisation application for a biocidal product containing 3-iodo-2-propynylbutylcarbamate (IPBC) PT 8

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

The BPC members discussed whether two formulation types would be acceptable for this particular single biocidal product application since during the opinion forming process the applicant clarified the use of the product for double vacuum/vacuum processes, i.e., the product is diluted in water before the use. Consequently, the formulation type AL (any other liquid) could not be applied for this specific use and the eCA proposed to apply an additional formulation type SL (soluble concentrate). During the discussion, the same criteria on acceptance of two formulation types were considered as discussed under agenda point 8.3. The BPC members agreed to accept two formulation types which then should be clearly recorded in the PAR relevant sections as well as the SPC section – formulation type – using from the drop down list in the SPC Editor the category “other”. By accepting the additional formulation type additional data need to be submitted to address technical properties of the product for formulation type SL and have to be included in information requested for post-authorisation (persistent foaming, degree of dissolution and dilution stability). This approach was supported by the members. The BPC members agreed on the formulation type and the re-inclusion of the use of the biocidal product for double vacuum pressure impregnation was accepted.

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

Actions:

- **Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **1 July 2022.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **29 July 2022**.

8.11 Draft BPC opinion on an Union authorisation application for a biocidal product family containing Chlorocresol PT 2, 3

The Chair welcomed the applicant. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the dossier. The biocidal product family (BPF) consists of 8 Meta-SPCs and 20 uses, out of which one Meta-SPC and one use was proposed for authorisation in the BPC opinion.

A member raised an issue related to exceedance of the maximum residue limit (MRLs) for livestock risk assessment. The member noted also that the studies that were applied for this BPF are not suitable, since no metabolites were analyzed, and there are no studies available on residues in milk and eggs. Without more suitable studies the risk assessment presented in the PAR is not considered acceptable. It was explained by the SECR that this issue had been discussed in detail during the Human Health Working Group where the majority agreed with the risk assessment performed by the eCA. The COM noted that there is still an ongoing Article 36 process based on a formal referral related to the same issue and there is no outcome for it yet. Therefore, for the time being there is no basis to re-discuss the conclusions of the Working Group. It was concluded not to change the existing assessment in the PAR nor in the BPC opinion.

Another point of discussion was related to new data provided by the applicant on metal corrosivity, which was identified as a data gap during the APCP Working Group and which would lead to the proposal for non-authorisation for a large part of the BPF. However, it was decided by the Working Group not to request any new data. The applicant submitted new data before the BPC meeting and the eCA considered these acceptable. Based on the provided data, 5 more Meta-SPCs were proposed to be authorised. The Chair noted that the submission of new data is not in line with the existing working procedure, and it was explained by the APCP WG Chair and the case expert that new data were not requested because the applicant would not be able to provide them within the 10 days deadline. The eCA and two member states supported the acceptance of the data, noting that non-authorisation decision based on missing metal corrosivity studies is disproportional, especially since there is no effect on the outcome of the risk assessment. Three member states were against accepting the new data, noting that there has been no peer-review process and a revised SPC was not available. Moreover, they had reservations related to not following the established working procedure, and some concerns were raised regarding equal treatment of applicants. The Chair concluded in favour of the proposal of the rapporteur. Therefore, the adoption of the opinion was postponed and the revised opinion will be adopted via a written procedure.

Actions:

- **Rapporteur:** to revise the product assessment report (PAR), draft SPC and the draft opinion in accordance with the discussions in the BPC and submit to the SECR
- **SECR:** to organise the follow-up consultation with the BPC members and the consequent opinion adoption in the next BPC meeting.

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

9.1. Draft BPC opinion on the evaluation of the availability and suitability of alternatives to hexaflumuron for PT 18

The Chair welcomed the applicant. The stakeholders were allowed to be present during the discussion. The rapporteur reported the changes performed in this version update. The BPC members acknowledged the improvement.

It was reminded that the purpose of this opinion is to identify the availability of suitable alternatives against the termite species targeted by hexaflumuron. The purpose is not to identify which alternative is best nor to provide an opinion on the renewal of hexaflumuron, the latter issue being dealt with separately.

The main following issues were discussed and clarified:

- There are no hexaflumuron-based products authorised yet on the EU market under the BPR rules, however, there are products authorised in Portugal, Spain, France and Greece under the transitional period (Art. 89 of the BPR). Applications under the BPR are currently under evaluation by the Portuguese, Spanish and French CAs (mutual recognition);
- The Netherlands had submitted information that no hexaflumuron-based products are authorised on their national market;
- Comparison of efficacy data of products is challenging when these have not been authorised under the same regime (hexaflumuron: BPD vs. diflubenzuron: BPR);
- The renewal of hexaflumuron may be possible even if there are currently no products authorised under the BPR;
- Particular climate conditions pertaining to the Canary Islands (hot and humid) seem to lead to high growth rates of *Reticulotermes Flavipes*. In this context products based on hexaflumuron have been preferred to control the colonies. The efficacy of diflubenzuron-based products could not be demonstrated in these conditions.
- The absence of efficacy data for diflubenzuron against tropical termites does not mean that this active substance would be non-efficacious against these species;
- No renewal application for fipronil has been received to date and is not expected to be received.

It was also requested that the opinion would clarify why some alternatives concluded to be non-suitable have nevertheless products available on the market and that a clearer conclusion should be added to the opinion regarding the availability of suitable alternatives to hexaflumuron, specifying the termite species.

The agreed general conclusion is that diflubenzuron is a suitable and available alternative to hexaflumuron for non-tropical termites and in non-tropical climate conditions. It is highlighted that this conclusion is not based on evidence that diflubenzuron is not

efficacious against tropical termite but is based on the fact that there are no efficacy data available for diflubenzuron against these species (species names to be added in the final opinion).

The BPC agreed to have the above clarifications and conclusion added in the opinion.

Actions:

- **SECR:** to forward the adopted opinion to COM by **8 July 2022** and publish it on the ECHA website.

9.2 Draft BPC opinion on Reaction products of paraformaldehyde and 2 hydroxypropylamine (ratio 3:2) for PT 2, 6, 11, 12 and 13

Given the similarity of the substances "reaction products of paraformaldehyde and 2 hydroxypropylamine" ratio 1:1 and ratio 3:2 and the comments received, the agenda points 9.2 and 9.3 were discussed together.

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

The BPC discussed on the reasons for non concluding on the ED properties of both formaldehyde releasers, among other the technical and scientific challenges to perform further testing. It was concluded that the detailed reasoning needs to be included in the Assessment Report. Furthermore it was discussed – as proposed by a member – whether a condition in section 2.3 needs to be included due to the impossibility to conclude on the ED properties. The majority of the members did not support to introduce a condition based on this but supported a condition to minimise exposure as the active substance meets the exclusion criteria.

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

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **1 July 2022**.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion to COM by **8 July 2022** and publish it on the ECHA website.

9.3 Draft BPC opinion on Reaction products of paraformaldehyde and 2 hydroxypropylamine (ratio 1:1) for PT 2, 6, 11 and 13

See agenda item 9.2 above.

The opinions were adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **1 July 2022**.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.

- **SECR:** to forward the adopted opinion to COM by **8 July 2022** and publish it on the ECHA website.

10. Any other business

There were no issues raised under this agenda item.

11. Agreement of the action points and conclusions

Part II contains the main conclusions and action points which were agreed at the meeting.

Part II - Main conclusions and action points

Main conclusions and action points

Main conclusions and action points

Agreed at the 43rd meeting of BPC
8-9 and 14-16 June 2022

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom / by when)**
Item 2 - Agreement of the agenda	
The final draft agenda was agreed without changes.	**SECR:** to upload the agreed final agenda to the BPC Website/Interact as part of the draft meeting minutes after the meeting.
Item 4 - Agreement of the minutes and review of actions from BPC-42	
The revised version of the minutes of BPC-42 was agreed.	**SECR:** to upload the agreed minutes to the BPC Interact and to the ECHA website.
Item 5 – Administrative issues	
5.1 Interact Security rules	
The BPC took note of the presentation provided by the SECR.	**SECR:** to upload the presentation on Interact.
Item 6 - Work programme for BPC	
6.1 BPC Work Programmes for active substance approval, Union authorisation, ED assessment and outlook for BPC	
-	**Members:** to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by **01 July 2022.**
6.2 Update on active substance approval and Union authorisation	
The BPC took note of the presentation provided by the SECR and agreed on some of the questions raised in it.	**SECR:** to upload the presentation on Interact/BPC CIRCABC IG.

Item 7 - Applications for approval of active substances	
7.1 Draft BPC opinion on Formic Acid for PT 2, 3, 4, 5 and 6	
The BPC adopted by consensus the opinion on the approval of the active substance for PT 2, 3, 4 and 5. The BPC adopted by majority the opinion on the approval of the active substance for PT 6.	**Rapporteur**: to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR by **29 July 2022.** **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **Member (SE):** to submit the minority position on PT 6 by **23 June 2022** **SECR:** to forward the adopted opinions to COM by **8 July 2022** and publish it on the ECHA website.
Item 8 – Union authorisation	
8.1 Revised working procedure for Union authorisation applications, revised working procedure for Linguistic review of SPC translations for Union authorisation, working procedure for linguistic review of SPC translation for same biocidal product applications for Union authorisation and the involvement of the applicant in the opinion forming process	
The BPC agreed on the revised working procedure for Union authorisation and the revised working procedure for the linguistic review of SPC translations. The BPC discussed the document on the involvement of the applicant in the opinion forming process.	**SECR:** i) to finalise the working procedures for Union authorisation applications and the linguistic review of SPC translations for Union authorisation and publish them on the ECHA web site; ii) to open a Newsgroup with a dead-line of **31 July 2022** for the document on the involvement of the applicant in the opinion forming process; iii) to inform the BPC at the next meeting on the linguistic review of SPC translations for SBP applications for Union authorisation.
8.2 Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from chlorine PT 2, 5	
The BPC adopted by majority the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **01 July 2022.** **Member (DE):** to submit the minority position by **23 June 2022.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **16 August 2022.**

8.3 Draft BPC opinion on an Union authorisation application for a biocidal product containing calcium dihydroxide / calcium hydroxide / caustic lime / hydrated lime / slaked lime PT 2, 3	
The BPC adopted by majority the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **01 July 2022.** **Member (DE):** to submit the minority position by **23 June 2022.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **16 August 2022.**
8.4 Draft BPC opinion on an Union authorisation application for a biocidal product containing calcium oxide / lime / burnt lime / quicklime PT 2, 3	
The BPC adopted by majority the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **01 July 2022.** **Member (DE):** to submit the minority position by **23 June 2022.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **16 August 2022.**
8.5 Draft BPC opinion on an Union authorisation application for a biocidal product family containing Peracetic acid PT 2, 3, 4	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **01 July 2022.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish the opinion on the ECHA website.

	Rapporteur: to submit the final non-confidential PAR to the SECR by **16 August 2022.**
8.3 Draft BPC opinion on an Union authorisation application for a biocidal product family containing Hydrogen peroxide PT 2	
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) in accordance with the discussions in the BPC and submit to the SECR by **01 July 2022.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion and final PAR to COM by **8 July 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **16 August 2022.**
8.4 Draft BPC opinion on an Union authorisation application for a biocidal product family containing Hydrogen peroxide PT 2, 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 **01 July 2022.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **16 August 2022.**
8.5 Draft BPC opinion on an Union authorisation application for a biocidal product family containing L-(+)-lactic acid PT 3, 4	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **01 July 2022.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **16 August 2022.**

8.6 Draft BPC opinion on an Union authorisation application for a biocidal product family containing L-(+)-lactic acid PT 2, 3, 4	
The BPC adopted by majority the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **01 July 2022.** **Member (DK):** to submit the minority position by **23 June 2022.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **16 August 2022.**
8.10 Draft BPC opinion on an Union authorisation application for a biocidal product containing 3-iodo-2-propynylbutylcarbamate (IPBC) PT 8	
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 **01 July 2022.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **8 July 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **16 August 2022.**
8.11 Draft BPC opinion on an Union authorisation application for a biocidal product family containing Chlorocresol PT 2, 3	
The BPC postponed the adoption of the opinion	**SECR:** to consult the eCA on the further process: either adoption via written procedure or in the next BPC.
Item 9 – Article 75(1)(g) opinion requests	
9.1 Draft BPC opinion on the evaluation of the availability and suitability of alternatives to hexaflumuron for PT 18	
The BPC adopted by consensus the opinion.	**SECR:** to revise the draft opinion in accordance with the discussions in the BPC. **SECR:** to forward the adopted opinion to COM by **8 July 2022** and publish it on the ECHA website.

9.2 Draft BPC opinion on Reaction products of paraformaldehyde and 2 hydroxypropylamine (ratio 3:2) for PT 2, 6, 11, 12 and 13	
The BPC adopted by consensus the opinions on the approval of the active substance PT combinations.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **29 July 2022.** **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinions to COM by **8 July 2022** and publish it on the ECHA website.
9.3 Draft BPC opinion on Reaction products of paraformaldehyde and 2 hydroxypropylamine (ratio 1:1) for PT 2, 6, 11 and 13	
The BPC adopted by consensus the opinions on the approval of the active substance PT combinations.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **29 July 2022.** **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinions to COM by **8 July 2022** and publish it on the ECHA website.
Item 11 – Any other business	

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Part III - List of Attendees

Members	Advisors
BALDASSARRI Lucilla (IT)	ALTMANN Dominik (AT)
BORG GALEA Joanne (MT)	AMPATZI Argyro (GR)
BORGES Teresa (PT)	ANKE Julia Margaretha (DE)
BROVKINA Julija (LV)	ASK BJÖRNBERG Karolin (SE)
CEBASEK Petra (SI)	BARTH Eva (DE)
CHEZEAU Aurelie (FR)	BODERO Marcia (NL)
GONZALEZ MARQUEZ Maria Luisa (ES)	CHMELIKOVA Jana (SK)
GREGERSEN Nina Falk (DK)	COLLET Romy (FR)
HADJIGEORGIOU Andreas (CY)	DE RIVAS Ana (ES)
HAHLBECK Edda (SE)	DEDEN Tobias (DE)
HAKAITE Palmira (LT)	DUH Darja (SI)
JARRETY Helene (BE)	EHNI Markus (DE)
JOHN Nina (AT)	GIATROPOULOS Athanasios (GR)
KOIVISTO Sanna (FI)	HOELZL Christine (AT)
MERISTE Anu (EE)	HOLTHENRICH Dagmar (DE)
MIKOLAS Jan (CZ)	JAEGER Stefanie (DE)
MIKOLASKOVA Denisa (SK)	LEPAGE Anne (BE)
RZODECZKO Helena (PL)	LEROY Celine (BE)
SZENTGYORGYI Timea (HU)	LUIJK Rebekka (NL)
TENTSCHER Peter (DE)	MATTHES Susann (DE)
VAGIAS Vasileios (EL)	PARR Mervyn (IE)
VRHOVAC FILIPOVIC Ivana (HR)	PIERCE Louise (IE)
ZIGRAND Jeff (LU)	PILIŠIOVÁ Ruzena (SK)
Alternate members	RUIZ LOPEZ Elena Fuensanta (ES)
GAUSTAD Astrid (NO)	SULG Helen (EE)
KALKERS Lucas (NL)	TALHOUËT Anne-Claire (FR)
MALLIA Lothar Paul (MT)	VAN DRIEL Ruud (NL)
PÜRGY Reinhild (AT)	WARMERDAM Sonja (NL)
PYTHON Francois (CH)	**Commission Observers**
RIFFAUT Lea (FR)	CHATELIN Ludovic (DG SANTE)
WEINHEIMER Viola (DE)	CAINZOS GARCIA Marta (DG SANTE)
	DELVAUX Vincent (DG SANTE)

GRUHN Lena (DG SANTE)	**ECHA Staff**
TSIAMIS Konstantinos (DG SANTE)	BUCHANAN Camilla
Accredited Stakeholder Observers	CARLON Claudio
CAZELLE Elodie	DE WOLF Watze
DREVE Simina	ESTEVAN MARTINEZ Carmen
VAN BERLO Boris	HÄMÄLÄINEN Eva
WEISS Aharon	HONKA Anni
WU Yuhua	JARDIN Helene
Applicants	KREBS Bernhard
BASF SE	MACKEVICA Aiga
ERM Regulatory Services Limited	MARCON Eva
C+S Chlorgas GmbH	MOTTET Denis
CID LINES NV	MUELLER Gesine
Corteva Agriscience International Sàrl	RAULIO Mari
European Lime Association aisbl	ROCKE Timo
Evonik Operations GmbH	SAEZ RIBAS Monica
Fraunhofer ITEM Biocides	STASKO Jolanta
SALVECO S.A.S.	SZYMANKIEWICZ Katarzyna
spectra Consult GmbH (on behalf of CVAS)	UPHOFF Andreas
TROY CHEMICAL COMPANY BV	VAN DE PLASSCHE Erik
Unilever Europe BV	VAN GALEN Joost
	VASILEVA Katya

Part IV - List of Annexes

Annex I List of documents submitted to the members of the Biocidal Products Committee

Annex II Final agenda of BPC-43

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-43 meeting

Agenda Point	Number	Title		
2.	BPC-A-43-2022_rev1	Draft agenda		
4.	BPC-M-42-2021	Draft minutes from BPC-42		
5.1	Presentation BPC-43-room_doc3	Administrative issues and report from the other Committees Interact security rules		
6.1	BPC-43-2022-01 BPC-43-2022-02 BPC-43-2022-03 BPC-43-2022-04	BPC Work Programmes for active substance approval, Union authorisation, outlook for BPC and ED assessment		
6.2	Presentation	Update on active substance approval and Union authorisation		
8.1	BPC-43-2022-10A, B, C, D	Revised working procedure for Union authorisation applications and revised working procedure for Linguistic review of SPC translations for Union authorisation		
10.		Any other business		
Agenda Point	**Number**	**Substance-PT**	**eCA**	**Title**
7.1	BPC-43-2022-05A	Formic Acid for PT 2	BE	Draft BPC opinion
	BPC-43-2022-05B			Assessment report
	BPC-43-2022-05C			Open issues
	BPC-43-2022-06A	Formic Acid for PT 3		Draft BPC opinion
	BPC-43-2022-06B			Assessment report
	BPC-43-2022-06C			Open issues
	BPC-43-2022-07A	Formic Acid for PT 4		Draft BPC opinion
	BPC-43-2022-07B			Assessment report
	BPC-43-2022-07C			Open issues
	BPC-43-2022-08A	Formic Acid for PT 5		Draft BPC opinion
	BPC-43-2022-08B			Assessment report

	BPC-43-2022-08C			Open issues
	BPC-43-2022-09A	Formic Acid for PT 6		Draft BPC opinion
	BPC-43-2022-09B			Assessment report
	BPC-43-2022-09C			Open issues
	Room documents_1	Formic Acid for PT 2, 3, 4, 5, 6		DocIII_DocIV_zip_files (4)
8.2	BPC-43-2022-11A	active chlorine released from chlorine	SI	Draft BPC opinion
	BPC-43-2022-11B			SPC
	BPC-43-2022-11C			PAR
	BPC-43-2022-11D			PAR Conf Annex
	BPC-43-2022-11E			Open issues
8.3	BPC-43-2022-12A	calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime	FR	Draft BPC opinion
	BPC-43-2022-12B			SPC
	BPC-43-2022-12C			PAR
	BPC-43-2022-12D			PAR Conf Annex
	BPC-43-2022-12E			Open issues
	BPC-43-2022-12F_13F			FR position paper virucidal claims
8.4	BPC-43-2022-13A	calcium oxide/lime/burnt lime/quicklime	FR	Draft BPC opinion
	BPC-43-2022-13B			SPC
	BPC-43-2022-13C			PAR
	BPC-43-2022-13D			PAR Conf Annex
	BPC-43-2022-13E			Open issues
	BPC-43-2022-_12F_13F			FR position paper virucidal claims
8.5	BPC-43-2022-14A	Peracetic acid	BE	Draft BPC opinion
	BPC-43-2022-14B			SPC
	BPC-43-2022-14C			PAR
	BPC-43-2022-14D			PAR Conf Annex
	BPC-43-2022-14E			Open issues
8.6	BPC-43-2022-15A	Hydrogen peroxide (BC-MS029571-20)	DE	Draft BPC opinion
	~~BPC-43-2022-15B~~			~~SPC~~
	BPC-43-2022-15C			PAR
	BPC-43-2022-15D			PAR Conf Annex
	BPC-43-2022-15E			Open issues
	BPC-43-2022-15F			Position paper

	BPC-43-2022-15G			Prof_Use_Expo_Assess
	BPC-43-2022-15H			Scenario 4_general public
8.7	BPC-43-2022-16A	Hydrogen peroxide (BC-UE029056-42)	NL	Draft BPC opinion
	BPC-43-2022-16B			SPC
	BPC-43-2022-16C			PAR
	BPC-43-2022-16D			PAR Conf Annex
	BPC-43-2022-16E			Open issues
	BPC-43-2022-16F			eCA_note_renumbering_Meta_SPC
8.8	BPC-43-2022-17A	L-(+)-lactic acid (BC-XR051157-11)	SI	Draft BPC opinion
	BPC-43-2022-17B			SPC
	BPC-43-2022-17C			PAR
	BPC-43-2022-17D			PAR Conf Annex
	BPC-43-2022-17E			Open issues
8.9	BPC-43-2022-18A	L-(+)-lactic acid (BC-HC051278-51)	FR	Draft BPC opinion
	BPC-43-2022-18B			SPC
	BPC-43-2022-18C			PAR
	BPC-43-2022-18D			PAR Conf Annex
	BPC-43-2022-18E			Open issues
8.10	BPC-43-2022-19A	3-iodo-2-propynylbutylcarbamate (IPBC)	DK	Draft BPC opinion
	BPC-43-2022-19B			SPC
	BPC-43-2022-19C			PAR
	BPC-43-2022-19D			PAR Conf Annex
	BPC-43-2022-19D1			PAR Conf Annex MS ONLY
	BPC-43-2022-19E			Open issues
	BPC-43-2022-19F			Discussion paper
8.11	BPC-43-2022-20A	Chlorocresol	FR	Draft BPC opinion
	BPC-43-2022-20B			SPC
	BPC-43-2022-20C			PAR
	BPC-43-2022-20D			PAR Conf Annex
	BPC-43-2022-20E			Open issues
	BPC-43-2022-20F			ANNEX_RISK for ANIMAL
9.1	BPC-43-2022-21A	Art. 75(1)(g) evaluation of the availability and suitability of	EL	Draft BPC opinion
	BPC-43-2022-21B			Open issues
	BPC-43-2022-21C			INFORME_Ministerio

	BPC-43-2022-21_room_doc2	alternatives to hexaflumuron for PT 18		Comparison document
	BPC-43-2022-21_room_doc3			Documentation relating to the comparison
9.2	BPC-43-2022-22A	Art. 75(1)(g) Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) for PT 2, 6, 11, 12 and 13	AT	Draft BPC opinion (PT2)
	BPC-43-2022-23A			Draft BPC opinion (PT6)
	BPC-43-2022-24A			Draft BPC opinion (PT11)
	BPC-43-2022-25A			Draft BPC opinion (PT12)
	BPC-43-2022-26A			Draft BPC opinion (PT13)
	BPC-43-2022-22B-26B			Assessment report
	BPC-43-2022-22C-26C			Open issues
	BPC-43-2022-27			Doc_II_A
	BPC-43-2022-28			Doc_II_A_appendix_1
	BPC-43-2022-29			Doc_II_A_appendix_2
	BPC-43-2022-30			Doc_II_A_appendix_HPA
	BPC-43-2022-31			Doc_III_A
9.3	BPC-43-2022-32A	Art. 75(1)(g) Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) for PT 2, 6, 11 and 13	AT	Draft BPC opinion (PT2)
	BPC-43-2022-33A			Draft BPC opinion (PT6)
	BPC-43-2022-34A			Draft BPC opinion (PT11)
	BPC-43-2022-35A			Draft BPC opinion (PT13)
	BPC-43-2022-32B-35B			Assessment report
	BPC-43-2022-32C-35C			Open issues
	BPC-43-2022-36			Doc_II_A
	BPC-43-2022-37			Doc_II_A_appendix_1
	BPC-43-2022-38			Doc_II_A_appendix_2
	BPC-43-2022-39			Doc_II_A_appendix_HPA
	BPC-43-2022-40			Doc_III_A

19 May 2022
BPC-A-43-2022_rev1

Draft agenda

43rd meeting of the Biocidal Products Committee (BPC)

8-9 and 14-16 June 2022

Meeting is held virtually via WebEx

Starts on 8 June at 10:30, ends on 16 June at 17:00

The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-43-2022_rev1

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-42

BPC-M-42-2022

For agreement

5. – Administrative issues

5.1. Administrative issues

For information

6. – Work programme for BPC

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

BPC-43-2022-01; BPC-43-2022-02; BPC-43-2022-03; BPC-43-2022-04

For information

6.2. Update on active substance approval and Union authorisation

For information

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

7.1. Draft BPC opinion on Formic Acid for PT 2, 3, 4, 5 and 6

Previous discussion: WG-I-2022

BPC-43-2022-05A, B, C
BPC-43-2022-06A, B, C
BPC-43-2022-07A, B, C
BPC-43-2022-08A, B, C
BPC-43-2022-09A, B, C

For adoption

8. – Union authorisation[**]

8.1.

e. Revised working procedure for Union authorisation applications

BPC-43-2022-10A

For agreement

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

BPC-43-2022-10B

For discussion

g. Revised working procedure for linguistic review of SPC translations for Union authorisation

BPC-43-2022-10C

For agreement

h. Working procedure for linguistic review of SPC translations for same biocidal products applications for Union authorisation

BPC-43-2022-10D

For agreement

8.2. Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from chlorine PT 2, 5

Previous discussion: WG-I-2022

BPC-43-2022-11A, B, C, D, 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).

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

8.3. Draft BPC opinion on an Union authorisation application for a biocidal product containing calcium dihydroxide / calcium hydroxide / caustic lime / hydrated lime / slaked lime PT 2, 3

Previous discussion: WG-I-2022

BPC-43-2022-12A, B, C, D, E, F

For adoption

8.4 Draft BPC opinion on an Union authorisation application for a biocidal product containing calcium oxide / lime / burnt lime / quicklime PT 2, 3

Previous discussion: WG-I-2022

BPC-43-2022-13A, B, C, D, E, F

For adoption

8.5 Draft BPC opinion on an Union authorisation application for a biocidal product family containing Peracetic acid PT 2, 3, 4

Previous discussion: WG-I-2022

BPC-43-2022-14A, B, C, D, E

For adoption

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

Previous discussion: WG-I-2022

BPC-43-2022-15A, C, D, E, F G, H

For adoption

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

Previous discussion: WG-I-2022

BPC-43-2022-16A, B, C, D, E, F

For adoption

8.8 Draft BPC opinion on an Union authorisation application for a biocidal product family containing L-(+)-lactic acid PT 3, 4

Previous discussion: WG-I-2022

BPC-43-2022-17A, B, C, D, E

For adoption

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

Previous discussion: WG-I-2022

BPC-43-2022-18A, B, C, D, E

For adoption

8.10 Draft BPC opinion on an Union authorisation application for a biocidal product containing 3-iodo-2-propynylbutylcarbamate (IPBC) PT 8

Previous discussion: WG-I-2022

BPC-43-2022-19A, B, C, D, D1, E, F

For adoption

8.11 Draft BPC opinion on an Union authorisation application for a biocidal product family containing Chlorocresol PT 2, 3

Previous discussion: WG-I-2022

BPC-43-2022-20A, B, C, D, E, F

For adoption

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

9.1 Draft BPC opinion on the evaluation of the availability and suitability of alternatives to hexaflumuron for PT 18

BPC-43-2022-21A, B, C

For adoption

9.2 Draft BPC opinion on Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) for PT 2, 6, 11, 12 and 13

Previous discussion: BPC-21

BPC-43-2022-22A, B, C
BPC-43-2022-23A, B, C
BPC-43-2022-24A, B, C
BPC-43-2022-25A, B, C
BPC-43-2022-26A, B, C
BPC-43-2022-27
BPC-43-2022-28
BPC-43-2022-29
BPC-43-2022-30
BPC-43-2022-31

For adoption

9.3 Draft BPC opinion on Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) for PT 2, 6, 11 and 13

Previous discussion: BPC-21

BPC-43-2022-32A, B, C
BPC-43-2022-33A, B, C
BPC-43-2022-34A, B, C
BPC-43-2022-35A, B, C
BPC-43-2022-36
BPC-43-2022-37
BPC-43-2022-38
BPC-43-2022-39
BPC-43-2022-40

For adoption

10. - Any other business

11.– Action points and conclusions

Provisional time schedule for the

43rd meeting of the Biocidal Products Committee (BPC)

Virtual meeting via WebEx

8 June 2022: starts at 10:30; 16 June 2022 ends at 17:00

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

Wednesday 8 June: (starts at 10:30 EET / 09:30 CET, ends at 18:00 EET / 17:00 CET)

Items 1-5	Opening items and administrative issues
Item 6.1	BPC Work Programmes for active substance approval, Union authorisation, ED assessment and outlook for BPC
Item 6.2	Update on active substance approval and Union authorisation
Item 7.1	Draft BPC opinion on Formic Acid for PT 2, 3, 4, 5 and 6
Item 9.2	Draft BPC opinion on Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) for PT 2, 6, 11, 12 and 13 (former MBO)
Item 9.3	Draft BPC opinion on Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) for PT 2, 6, 11 and 13 (former HPT)

Thursday 9 June : (starts at 10:30 EET / 09:30 CET, ends at 18:00 EET / 17:00 CET)

Item 9.1	Draft BPC opinion on the evaluation of the availability and suitability of alternatives to hexaflumuron for PT 18
Item 8.1	Revised working procedure for Union authorisation applications and revised working procedure for Linguistic review of SPC translations for Union authorisation
Item 8.2	Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from chlorine PT 2, 5 (BC-EQ047299-18)

Tuesday 14 June: (starts at 10:30 EET / 09:30 CET, ends at 18:00 EET / 17:00 CET)

Item 8.3	Draft BPC opinion on an Union authorisation application for a biocidal product containing calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime PT 2, 3 (BC-JR038510-32)
Item 8.4	Draft BPC opinion on an Union authorisation application for a biocidal product containing calcium oxide/lime/burnt lime/quicklime PT 2, 3 (BC-VJ038509-19)
Item 8.7	Draft BPC opinion on an Union authorisation application for a biocidal product family containing Hydrogen peroxide PT 2, 4 (BC-UE029056-42)

Wednesday 15 June: (starts at 10:30 EET / 09:30 CET, ends at 18:00 EET / 17:00 CET)

Item 8.6	Draft BPC opinion on an Union authorisation application for a biocidal product family containing Hydrogen peroxide PT 2 (BC-MS029571-20)
Item 8.8	Draft BPC opinion on an Union authorisation application for a biocidal product family containing L-(+)-lactic acid PT 3, 4 (BC-XR051157-11)

Item 8.9	Draft BPC opinion on an Union authorisation application for a biocidal product family containing L-(+)-lactic acid PT 2, 3, 4 (BC-HC051278-51)

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

Item 8.5	Draft BPC opinion on an Union authorisation application for a biocidal product family containing Peracetic acid PT 2, 3, 4 (BC-EW057176-14)
Item 8.10	Draft BPC opinion on an Union authorisation application for a biocidal product containing 3-iodo-2-propynylbutylcarbamate (IPBC) PT 8 (BC-QN044827-14)
Item 8.11	Draft BPC opinion on an Union authorisation application for a biocidal product family containing Chlorocresol PT 2, 3 (BC-RF039183-42)
Item 11	Action points and conclusions

End of meeting

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