5 May 2022

BPC-M-41-2021

Non-confidential minutes of the 41st meeting of the Biocidal Products Committee (BPC)

29 November - 3 December 2021

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chair of the Biocidal Products Committee (BPC) welcomed the participants to the 41st BPC meeting which took place as a virtual meeting via Webex.

The Chair then informed the BPC members of the participation of 28 members, including three alternate members.

29 Advisers (of whom 3 in double role also as an alternate member) and 6 representatives from an accredited stakeholder organisation (ASO) were present at the meeting. Three 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 and Article 75(1)(g) items under agenda item 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-41-2021_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 CIRCABC IG 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-40

The revised draft minutes from BPC-40 (BPC-M-402021), incorporating the comments received, were agreed.

The Chair mentioned that all actions from the previous BPC-40 meeting were carried out.

Actions:

- **SECR:** to upload the agreed minutes from BPC-40 to the BPC S-CIRCABC IG 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-42 as a face-to-face meeting.

5.2. Experience in using Interact Collaboration Tool

The SECR gave a short presentation on recent actions and future directions in using Interact Collaboration Tool for commenting. As a solution for the encountered problems SECR has onboarded more users and will communicate to the BPC members on how to nominate more users. A pilot will be performed with an excel template for commenting, member states are called to volunteer for this pilot.

Actions for SECR:

- Provide information on how to onboard new users;
- Launch a pilot with the new excel template for commenting.

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 2021 the planned opinions are listed in the “Outlook” document. The total number of adopted opinions will be comparable to 2020: 41 versus 38. The number for UA increased from 10 to 15 and for the Review Programme from 15 to 16.

The Chair asked the evaluating Competent Authorities being rapporteur for active substances or Union authorisations scheduled for discussion at the the first BPC meeting of 2022 (BPC-42) 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 **10 December 2021**.

6.2. Update on active substance approval and Union authorisation

An update on Union authorisation (UA) and Active substance (AS) was given by the SECR: i) workload on AS and UA cases; ii) updates from processes, iii) information from the CG discussion on post-authorisation conditions.

i) Workload on AS and UA

SECR presented the current workload of AS and UA dossiers in peer-review. It was reminded that the cases planned to enter peer-review will increase significantly, starting from the first half of 2022. The SECR reminded MSs to update the planning

document provided via the Interact Collaboration tool if there are changes in MSs planning of submission of CARs/PARs.

ii) Update from AS and UA processes

In addition, the SECR reminded about the applicants legal rights for 30 days commenting before submission of CAR/PAR (Article 8(1) and Article 44(1) of the BPR). SECR reminded that for active substances approved with no reference specifications, a reference specification must be set at the time of renewal. A specific discussion will take place at the WG-I-2022 APCP meeting.

iii) Information from the CG discussion on post-authorisation conditions

SECR provided feedback from the CG-49 meeting where the CG agreed that the physical hazards and respective characteristics which affect product classification and labelling cannot be addressed by post-authorisation conditions and that post-authorisation conditions in exceptional cases are only possible for those physical, chemical and technical properties which would neither affect Article 19(1) conditions, nor the efficacy/risk assessment. The discussion in relation to shelf-life will be continued in the CG-50 meeting.

Actions:

- **SECR**: to upload the presentation to S-CIRCABC.

7. Applications for approval of active substances

7.1. Procedural and administrative aspects:

7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval

The Chair stated that no changes were introduced in the document compared to the version presented at BPC-40 and informed that in future meetings this item will only be added to the agenda if the document has been amended.

Actions:

- **Members:** To check the standard conditions when preparing opinions.

7.2. Draft BPC opinion on Ozone generated from oxygen for PT 2, 4, 5 and 11

The Chair welcomed the applicant for this item. The ASOs were not allowed to be present during the discussion. The rapporteur introduced the case.

The assessment report prepared for all PTs was agreed. The BPC opinions for PT 2, 4, 5 and 11 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 17 January 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 22 December 2021 and publish it on the ECHA website.

7.3. Draft BPC opinion on Alkyl (C12-16) dimethylbenzylammonium chloride (C12-16-ADBAC/BKC) for PT 1 and 2

The Chair welcomed the two applicants for this item. The ASOs were allowed to be present during the discussion. The Chair informed the BPC that a room document was provided by the eCA presenting combined tonnage calculations for both PTs, as part of the environment risk assessment.

The rapporteur briefly introduced the case stating that C_{12-16}-ADBAC/BKC PT 1 and 2 are backlog dossiers. PT8 is already approved under the BPD, whereas PT 3 and 4 are approved under the BPR.

The importance of information on resistance and cross resistance in the assessment report and opinion was pointed out.

Generally, it was agreed that QUATs lose their biocidal activity when used in combination with many anionics but this does not apply to all anionics. Therefore, this will need to be assessed on a case-by-case basis at product authorisation.

It was agreed that the request for a dietary risk assessment at product authorisation does not trigger automatically the need for analytical methods for residues in food.

In the peer-review, the eCA was asked to carry out a tonnage-based assessment for the total tonnage of the same use, summing up tonnages of the two applicants. This is the usual approach – where relevant for the PT – in case of multiple applicants. This tonnage-based assessment was not presented in the draft Final CAR, although it was provided upon request during the peer review. Only recently a TAB entry on how the tonnage-based approach should be performed was published after legal check. However, a tonnage-based approach as part of the environmental risk assessment is required since several years and a legal or procedural mistake did not occur.

The eCA presented a room document with the calculations to the BPC, to be kept strictly confidential and reserved to CAs only, showing no unacceptable risk in any of the environmental compartments for C12-16-ADBAC/BKC under PT 1. For PT 2 no unacceptable risk in any of the environmental compartments was found, except for soil, where a slight risk was evidenced. For each a.s./PT combination, the consumed-based assessment as well as the tonnage–based assessment carried separately for each applicant showed no unacceptable risk in any of the environmental compartments. The eCA argued that in the tonnage-based approach no dissipation or disintegration during use and during transport in the sewer to the STP was assumed, which is a worst-case consideration, leading for PT 2 to risk for soil, the value slightly exceeding 1. Further it was stated that C12-16-ADBAC/BKC is readily biodegradable, not persistent and is highly absorptive. It is likely that the substance will absorb in the sewer to larger particles which

may be removed in the first filtering step at the STP and disposed of. Some BPC members were of opinion that acceptable risk in a consumption-based assessment cannot be used as an argument for accepting risks as according to guidance the tonnage based risk assessment is the method to be used due to higher emissions. It is neither possible to refer to the separate tonnages as the tonnage based assessment should be based on the total tonnage according to the guidance. Some BPC members commented that despite the arguments brought forward by the eCA safe use could not be shown for PT 21. Also, there is the possibility that the tonnage will increase in future and tonnages cannot be restricted under the BPR. It was clarified that it might not be possible to apply RMM for PT 2. Other BPC members and the applicants were in support of the eCA arguing that the assessment is worst case, and it can be considered that there is no risk based on expert judgment.

All the other issues indicated in the open issues table were discussed and agreed. The assessment reports for PT 1 and 2 were agreed, and the BPC opinion for PT 1 was adopted by consensus. The BPC opinion for PT 2 was adopted by majority. Three members provided a minority position and one abstained.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR by **28 January 2021**.
- **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 (DE, SE, FI)**: to submit the minority position by **7 December 2021**.
- **SECR:** to forward the adopted opinions to COM by **22 December 2021** and publish them on the ECHA website.

7.4. Draft BPC opinion on *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide for PT 18 and 19

The Chair welcomed the applicants for this item. The ASOs were allowed to be present during the discussion.

Given the great similarity of the two *Chrysanthemum* extracts, obtained with supercritical carbon dioxide and obtained with hydrocarbon solvents, with many comments in common, the agenda items 7.4 and 7.5 were discussed together. The rapporteur briefly introduced the cases.

The applicants raised their concern on the inclusion of the plant material in the reference specifications as the composition of these extracts may change due to natural variations

[1] It was stated that dissipation or disintegration during use and transport in the sewer is not taken into account according to the guidance. These elimination mechanisms have so far been accepted only for oxidizing substances where C_{12-16}-ADBAC/BKC is not an oxidizing substance. Ready biodegradation, adsorption and non-persistency are taken into account in the exposure assessment but these did not reduce the environmental emissions to soil to an extent that no unacceptable risk is identified.

of the plant source. The applicants requested an increase of the range and submitted several questions on the components identified within the plant material. It was clarified that the plan material should be included in the reference specification as it is part of the substance although these constituents are not of (eco)toxicological relevance. The reference specifications were already agreed by the APCP WG where no quality control data was provided by the applicants that would allow to amend the reference specification. The Chair concluded that further discussion will take place trilaterally between the applicants, the eCA and ECHA related to questions concerning the possible need for applications for technical equivalence.

The BPC discussed requesting physical hazard data post approval. This situation resulted from the conclusion of the APCP WG that the solvent is not part of the substance, and therefore additional physical hazard data without the solvent are to be provided. The applicants informed that studies were already on-going. One members raised concerns over possible physical hazards. It was agreed to include the data in section 2.5 of the opinion as post-approval data with the recommendation to the eCA to evaluate the data as soon as possible to facilitate the further decision making process. In addition it was concluded that analytical methods in several matrices are required as post-approval data.

The main discussion was on the identified risks to sediment for the PT 18 applications. The discussions and agreements at the ENV WG on the model used, lead to a slight exceedance of a PEC/PEC ratio of 1 and subsequently a risk to sediment. The limited data available for sediment dwelling organisms and limitations of applying the model (the Equilibrium Partitioning Method or EPM) to assess the risk for this type of substances characterised by a very high Koc value, represents a worse case that leads to a considerable uncertainty. Therefore the eCA considered that this small risk to sediment could be reduced by the submission of further information or other – for example exposure - considerations and proposed to approve the substance.

The eCA indicated that information is available: a test with *Hyalella Azteca* provided by the applicant before the ENV WG (during the so-called trilaterals) when it appeared that there might be a risk to sediment. In addition, the eCA clarified that no risk mitigation measures could be idenfied. The eCA proposed the WG to consider these additional study which might reduce the assessment factor applied to derived the PNEC value and subsequently lead to an acceptable risk. The ENV WG did not accept to consider the study as the PNEC value was already agreed and it was not clear at that point in time if there would be a risk for sediment.

The applicant informed the BPC about two additional chronic studies on sediment swelling organisms which were on-going where results would be available in the beginning of 2022.

Several BPC members found it difficult to decide on such a critical situation without further information and discussions at WG level, because although the risk is small these substances are toxic to aquatic organisms. It was also indicated that further testing may not automatically lead to a higher PNEC value as the tested organisms may be less sensitive.

The BPC extensively discussed the possibility to accept the additional study provided during the process. It was clarified by the Chair and the Commission that such data related to environmental characteristics cannot be requested under section 2.5 of the opinion as without these data the assessment shows unacceptable risks. Referring to the earlier agreed BPC document “Introducing new information during the peer review process of active substance approval” it was concluded to accept the introduction of the study as it

was available at the time of the ENV WG meeting. Subsequently, the BPC concluded to postpone the discussion for PT 18 and ask the eCA to evaluate and incorporate the study in the evaluation.

There were no further discussions for PT 19. The BPC agreed on the Assessment Report for PT 19 and the opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report for PT 19 in accordance with the discussions in the BPC and submit to the SECR by 28 January 2021.
- **SECR:** to revise the draft opinion for PT 19 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 for PT 19 to COM by 22 December 2021 and publish it on the ECHA website.
- **SECR and rapporteur:** to consult on the further process for PT 18.

7.5. Draft BPC opinion on *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents for PT 18 and 19

As indicated under the agenda item 7.4 both *Chrysanthemum* extracts were discussed together.

The BPC concluded to postpone the discussion on PT 18 and ask the eCA to evaluate and incorporate the study in the evaluation.

The BPC agreed on the Assessment Report for PT 19 and the opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report for PT 19 in accordance with the discussions in the BPC and submit to the SECR by **28 January 2021**.
- **SECR:** to revise the draft opinion for PT 19 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 for PT 19 to COM by **22 December 2021** and publish it on the ECHA website.
- **SECR and rapporteur:** to consult on the further process for PT 18.

7.6. Draft BPC opinion on Didecyldimethylammonium chloride (DDAC) for PT 1 and 2

The Chair welcomed the two applicants for this item. The ASOs were allowed to be present during the discussion. The Chair informed the BPC that a room document was provided by the eCA presenting combined tonnage calculations for both PTs, as part of the environment risk assessment.

The rapporteur briefly introduced the case stating that DDAC PT 1 and 2 are backlog dossiers. PT8 is already approved under the BPD, whereas PT 3 and 4 are approved under the BPR.

The eCA presented the room document with the calculations to the BPC, to be kept strictly confidential and reserved to CAs only, showing no unacceptable risk in any of the environmental compartments for DDAC under PT 1 and PT 2.

All the other issues indicated in the open issues table were identical to issues discussed and agreed in the discussion for C_{12-16}-ADBAC/BKC PT 1 and 2. No further discussion took place. The assessment reports for PT 1 and 2 were agreed, and the BPC opinion for PT 1 and PT 2 was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR by **28 January 2021**.
- **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 **22 December 2021** and publish them on the ECHA website.

7.7. Revised Assessment Report following the submission of data after active substance approval:

Before starting the discussion one member expressed that they are against including in the LoEP data which are submitted during product authorisation for the following reasons:

- access to these data: a letter of access is needed in order to benefit from the data. If the data are now included in the LoEP, without highlighting this requirement, it is not transparent anymore, neither for the prospective applicants for product authorisation nor for the MSCAs involved in the evaluation of these product authorisations. Especially as often a LoA to the whole active substance dossier is received. This might not be an issue if this data is generated by the applicant of the active substance approval application as in the cases of this meeting, although the applicant may wish to negotiate the access to this data separately, but for sure for other parties which have generated data on the active substance.
- status of the LoEP: If it is the intention that the new data should be used for every application for product authorisation, which version of the LoEP shall be used for product evaluation if it is updated several times? It cannot be excluded that for the same active substance, new data will be submitted with a long time period in between. Is it needed to always reopen the assessment whenever a new version of the LoEP is available and check whether this has an impact on the conclusions?
- workload: there might be a lot of new data received during product authorisation, especially for the environment. If such data is submitted in different Member States, the assessment shall be agreed upon in a WG meeting, with no need to go to BPC, nor to update the LoEP. Those Member States who received the data or a LoA can then use the data for these applications, but

those applications where no LoA has been submitted shall of course not benefit from the data.

- notwithstanding the workload on the BPC that this procedure would bring, it can also cause long delays for product authorisation.
- last, to open the AR and LoEP for any new data submitted during product authorisation would also be in conflict with the procedures agreed for the active substance approval process as new data are not accepted any longer during the peer review process.

The member proposed that if the applicants of the active substance wish to include the data in the LoEP, they can submit the data for the renewal application of the active substance.

The Chair thanked the member for their view and alerted all the BPC members that this topic will be discussed at the next CA meeting. The Chair highlighted that the three cases concerned were placed on the agenda of the meeting as the evaluations were already agreed at the ENV WG a significant time ago where related product authorisation applications were on hold due to the fact that the data were not yet agreed at the BPC. It was decided that the result of the discussion at the CA meeting will be incorporated.

7.7.1. Permethrin

The Chair welcomed the applicant for this item. ASOs were not allowed to be present during the discussion.

The Netherlands CA informed the meeting that the data were received in a product authorisation application. These data were discussed and agreed upon in the ENV WG in June 2019.

One member provided the following comments, which will be taken into account:

- Doc IIIA – Evaluation by rapporteur member state:

  It is stated that the WG decided to exclude non-extractable residues from the evaluation. This is somewhat misleading, as the conclusion was to exclude NER from the DT50 derivation, but later include them as % of parent in the sludge in SimpleTreat.

- AR – 2.2.2.1. Fate and Distribution in the Environment & LoEP:

  The conclusion regarding the NER (see comment to Doc IIIA) shall be included in chapter 2.2.2.1. For the sake of completeness, the percentage of NER should be stated in the LoEP

The BPC accepted the post approval data submitted and agreed to the updated Assessment Report.

Actions:

- **Member (NL):** to forward the revised assessment report with the List of Endpoints to the SECR by **15 December 2021.**

7.7.2. Transfluthrin for PT 18

The Chair welcomed the applicant for this item. ASOs were not allowed to be present during the discussion.

The eCA informed that the data were received in a product authorisation application. These data were discussed and agreed upon in the ENV WG in April 2019.

One member provided the following comments, which will be taken into account:

- Doc IIA – Table 4.1.1.1.-2

  Correct the typos: The title of the table "Degradation of transfluthrin in aerobic water/sediment systems" is not correct and should be changed into "Degradation of transfluthrin in activated sludge." The formation fraction of trans-OH-DCVA is not 0.267 but 0.261. A statement regarding the amount of NER along with a justification for non-consideration should be added (see conclusion document of the RMS study evaluation revised in July 2019).

- AR – LoEP
  The k-rate derived from the DT50 of 0.284 d for transfluthrin is 0.102/h instead of 0.118/h. Please, correct.

The BPC accepted the post approval data submitted and agreed to the updated Assessment Report.

Actions:

- **Member (NL):** to forward the revised assessment report with the List of Endpoints to the SECR by **15 December 2021.**

7.7.3. Chlorocresol

ASOs were not allowed to be present during the discussion.

The Netherlands CA informed the meeting the data were received in a product authorisation application. These data were discussed and agreed upon in the ENV WG in September 2019. No comments were raised so the BPC accepted the post approval data submitted and agreed to the updated Assessment Report.

Actions:

- **Member (NL):** to forward the revised assessment report with the List of Endpoints to the SECR by **15 December 2021.**

8. Union authorisation

8.1. Draft BPC opinion on an Union authorisation application for a biocidal product family containing hydrogen peroxide

The Chair welcomed the applicant. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the dossier. The application is a re-submission where in the "first application" the product was not authorised as efficacy was not sufficiently demonstrated. The family is composed of a meta-SPC for which four intended uses are proposed for authorisation. The products are ready-to-use surface disinfectants in PT 2 to be used in cleanrooms.

It was pointed out that not all author and laboratory names from the study reports should be redacted automatically from the public PAR but only if requested and justified by the applicant.

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 **15 December 2021**.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **22 December 2021** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **28 January 2021**.

8.2. Draft BPC opinion on an Union authorisation application for a biocidal product family containing L-(+)-lactic acid

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

The Biocidal Product Family “Lactic acid based products – CID LINES NV” contains disinfectant products with L-(+)-lactic acid as active substance that belong to PT 1, PT 2, PT 3 and PT 4. In first instance the family was composed of fifteen meta-SPCs, however, during the evaluation unacceptable risks were identified for all products of one meta SPC. Therefore an authorisation was proposed for fourteen meta-SPCs.

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 **15 December 2021**.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **22 December 2021** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **28 January 2021**.

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

9.1. Draft BPC opinion on evaluation of the level of the risks for human health and for the environment of DBNPA used in biocidal products of product type 4

The Chair welcomed the applicant. The stakeholders were allowed to be present during the discussion. The rapporteur briefly introduced the dossier and the questions of the mandate.

Discussion took place on whether it can generally be assumed that for essential elements a threshold of adversity for the ED effects exists. Some members requested that a horizontal discussion should take place at EU level across different legislation. The DBNPA draft opinion identified several elements of uncertainties in the identification of a threshold eg. diverse debate among scientists is still ongoing and it is currently too early for general statements regarding the existence of a threshold for EDs. The same criteria across all legislations should apply. This is considered as part of the European Chemical Strategy for Sustainability which focuses on endocrine disrupting chemicals with the main attempt to minimise exposure as far as possible. Several members agreed that the opinion should reflect that the ED effects of DBNPA is attributed to bromide and this substance is an essential and widely occurring elemental substance and therefore a threshold of adversity must exist.

It was clarified that the assessment refers only to the PT 4 use of DBNPA as requested in the mandate, which was also confirmed by Commission. Whether the dietary average daily intake of bromide levels as presented in the opinion can be considered as safe or not was not evaluated. Therefore, no assumption can be made in this respect.

Some members considered the assessment rather as exposure assessment and not risk assessment. The eCA clarified that the exposure assessment was used in a qualitative way to assess additional risk due to DBNPA PT4 contribution.

The acceptability of risk due to additional exposure via DBNPA PT4 use was questioned referring to Article 5.2(a) where negligible risk is mentioned. COM clarified that conclusion on the negligibility of risk is not in the mandate of the BPC but the conclusion would need to be made by the Standing Committee.

Some concern was raised that a precedent for EDs could be set with the assessment proposed by the eCA, especially referring to the environmental assessment. The high variation in the bromide concentration in the environment should be considered, referring to areas with low natural bromide concentration where the bromide release due to DBNPA use could exceed the background concentration. The high level of remaining uncertainties in the assessment was mentioned. Other anthropogenic sources of bromide exist. It was not evaluated whether those concentrations are safe. However, it was clarified that the natural background variation can be in the range of anthropogenic sources and that adaptation of environmental species to the natural background can be assumed. It was also referred to the iodine assessment in the past where large variations in the background levels were accepted to be used in the assessment, although it was made clear that ED effects were not assessed at that time.

Commission clarified that in case the substance is eventually approved, biocidal products cannot be used by the general public according to Article 19.4 BPR since it is as endocrine disruptor.

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

The assessment report was agreed, and the BPC opinion was adopted via a voting procedure by majority. Three members abstained and two provided a minority position.

Actions:

- **Rapporteur:** to revise the assessment report - including the underlying report - in accordance with the discussions in the BPC and submit to the SECR by **15 December 2021**.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **Members (DE, SE)**: to submit the minority position by **7 December 2021**.
- **SECR:** to forward the adopted opinion to COM by **22 December 2021** and publish it on the ECHA website.

9.2. Draft BPC opinion on evaluation of the level of the risks for human health and for the environment of cyanamide used in biocidal products of product types 3 and 18

The Chair welcomed the applicant. The stakeholders were allowed to be present during the discussion.

The rapporteur introduced the dossier pointing out that cyanamide is a backlog dossier for which the principals of the BPD apply. Cyanamide is identified as endocrine disruptor following the EFSA/ECHA ED Guidance following which it is suggested to stop the ED assessment for human health when agreement can be reached on the ED criteria for one ED modality, in which case other ED modalities are not further investigated. Neither guidance nor a harmonised understanding on the principals of an ED risk assessment is available. Without the investigation of the remaining ED modalities a threshold cannot be identified. For non-target organisms, it was not possible to derive thresholds neither, although the reasons differ (diversity of non-target organisms and lack of suitable test methods). Since scientific tools for an ED risk assessment are missing, it is not possible to conclude if cyanamide containing biocidal products can be used safely or not. The decision if cyanamide can be approved has to be taken at policy level. The rapporteur stated further that any decision on cyanamide might set a precedent for further ED substances. This would be even more valid for substances, which were identified as ED only for the environment, as this hazard did not lead to flag the substance as exclusion candidate, but only as substitution candidate.

The rapporteur questioned whether it was the spirit of the BPR to not approve an active substance identified as an ED for the environment, while the tools were lacking to demonstrate a safe use. In the opinion of the rapporteur, a refusal of approval is not foreseen by the BPR as a consequence of the identification of an environmental ED and therefore, would set a precedent with long reaching implications for other substances in the future. The rapporteur further stated that, as no regulatory tools were available, one either had to decide that no conclusion can be drawn or all active substances identified as an ED for the environent would result in a non-approval decision without the option to derogate according to Art. 5 (2). According to the rapporteur's opinion, this is clearly not the intention of the BPR and the rapporteur encouraged the Commission to analyse the impact before proposing such a decision.

The applicant introduced the background document submitted on the day of the BPC discussion requesting a prolongation of the timeline and expressing willingness to generate new data on cyanamide. The applicant also pointed out that under the BPD the ED properties were not assessed. It was clarified that an extension of the deadline is not possible pointing out that the WGs did not request new data but could conclude on the data available. Commission clarified that although cyanamide is a backlog dossier, the level of risk needed to be identified also under the BPD, which included ED hazardous properties. The BPC clearly concluded on the ED properties of cyanamide. It was agreed that the opinion of the applicant can be reflected in the assessment report but not in the opinion.

One member commented that absence of guidance should not be used as justification for not concluding on the risk assessment. However, due to limited data a threshold could not be identified but a qualitative assessment might be possible. The applicant argued that the possibility to submit further data on non-target organism was not granted by the WG. To their view, the risk under the BPD is safe but not under the BPR which should be reflected in the assessment. The applicant further requested that new data on biodegradation in manure under realistic conditions can be submitted at product authorisation, since uncertainties regarding the available biodegradation data are reflected in the current assessment report. This request is due to the fact that the environmental risk assessment and the risk assessment for the general public is based on exposure considerations following manure application on soil. However, the ENV Working Group had already decided that new data would not overwrite the results of the already existing study and will not help to demonstrate that no releases to the environment occur. In relation to further ED studies on non-target organisms, Commission and the rapporteur pointed out that the substance was identified as ED for the environment by the BPC and its working groups based on the already available mammal studies, and therefore it was not considered necessary to request further data.

It was discussed if the acceptability of the risk for the general public should be further elaborated in the opinion and the rapporteur argued that the acceptability of the risk cannot be defined. It was further clarified that secondary exposure for the professional user is not relevant since no direct contact to the manure exist and since residues of the product are rinsed-off after application. The primary exposure of the professional user was considered safe as this user group did not comprise particularly sensitive sub-groups and appropriate risk mitigation measures were in place to ensure minimized exposure.

All the other issues indicated in the open issues table were discussed and agreed. The assessment report was agreed, and the BPC opinions for PT 3 and PT 18 were adopted by majority. One member provided a minority position.

Actions:

- **Rapporteur:** to revise the assessment report - including the underlying report - in accordance with the discussions in the BPC and submit to the SECR by **15 December 2021**.
- **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 **7 December 2021**.
- **SECR:** to forward the adopted opinion to COM by **22 December 2021** and publish it on the ECHA website.

9.3. Draft BPC opinion on eligibility of peanut butter active substance for inclusion into Annex I to the BPR

The stakeholders were allowed to be present during the discussion. The SECR as a rapporteur briefly introduced the dossier.

It was concluded that peanut butter is not eligible for inclusion in Annex I due to its immunitoxic properties. Several possible risk mitigation measures were discussed which can be used at the product authorisation stage. It was concluded to add these risk mitigation measures to the opinion, but indicate these are proposals to be considered further on.

Actions:

- **SECR:** to forward the adopted opinion to COM by **22 December 2021** and publish it on the ECHA website.

9.4. Draft BPC opinion on questions relating to a guidance on rodent traps developed by the German Environment Agency

The stakeholders were allowed to be present during the discussion. The SECR as a rapporteur briefly introduced the dossier.

There were a few general questions raised with reference to the NoCheRo guidance and future evaluation of ARs.

The Chair clarified that the NoCheRo guidance is a first step of introducing non-chemical alternatives in the forthcoming comparative assessment that is necessary to be performed for ARs during the renewal of authorisation process. It is expected that during upcoming public consultations more information about non-chemical alternatives will be provided and then possibly taken into consideration.

With reference to the certification system, it was clarified that it will be developed in the near future. The workshop addressing the certification scheme presented in the NoCheRo guidance is planned for 2022. Currently, in DE the mechanical traps are tested in accordance with the criteria listed in the NoCheRo guidance. The names of the traps, which passed these efficacy criteria will be listed on a dedicated UBA webpage.

The opinion was amended with reference to section 2.2.3: Test and target organisms, and section 2.2.4: Efficacy criteria. In section 2.2.3 a clarification concerning voles as test organisms was added to the opinion. In section 2.2.4 the sentence: "*In both guidance documents, efficacy is considered sufficient, if in semi-field test at least 90% of test organisms are achieved and at least 90% of the population is eradicated in a field* trial" is amended to: *"In both guidance documents, efficacy is considered sufficient, if in semi-field test at least 90% of test organisms accept the bait or trap and at least 90% of the population is eradicated in a field trial".*

The opinion was adopted by consensus.

Actions:

- **SECR:** to forward the adopted opinion to COM by **22 December 2021** and publish it on the ECHA website.

10. Any other business

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

Agreed at the 41st meeting of BPC

29 November – 3 December 2021

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 CIRCABC IG as part of the draft meeting minutes after the meeting.
Item 4 - Agreement of the minutes and review of actions from BPC-40	
The revised version of the minutes of BPC-40 was agreed.	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website.
Item 5 – Administrative issues	
5.2 Experience in using Interact Collaboration Tool	
The BPC discussed the item.	**SECR**: to upload the presentation on the experience in using Interact Collaboration Tool on CIRCABC IG. **SECR**: to consider the suggestions made by the members in the future use of the Interact Collaboration Tool.
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 **10 December 2021.**
6.2 Update on active substance approval and Union authorisation	
The BPC took note of the presentation provided by the SECR.	**SECR:** to upload the presentation on the BPC CIRCABC IG.

Item 7 - Applications for approval of active substances	
7.1 Procedural and administrative aspects:	
7.1.1 Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval	
The BPC took note of the document.	-
7.2 Draft BPC opinion on Ozone generated from oxygen for PT 2, 4, 5 and 11	
The BPC adopted by consensus the opinion 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 **28 January 2021.** **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 **22 December 2021** and publish them on the ECHA website.
7.3 Draft BPC opinion on Alkyl (C12-16) dimethylbenzylammonium chloride (C12-16-ADBAC/BKC) for PT 1 and 2	
The BPC adopted by consensus the opinion on the approval of the active substance for PT 1. The BPC adopted by majority the opinion on the approval of the active substance for PT 2.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **28 January 2021.** **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. **Members (SE, DE & FI):** to submit the minority position on PT 2 by **10 December 2021** **SECR:** to forward the adopted opinions to COM by **22 December 2021** and publish them on the ECHA website.
7.4 Draft BPC opinion on Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with supercritical carbon dioxide for PT 18 and 19	
The BPC postponed the adoption of the opinion on PT 18. The BPC adopted by consensus the opinion on the approval of the active substance for PT 19.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **28 January 2021.** **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 **22 December 2021** and publish them on the ECHA website.

7.5 Draft BPC opinion on Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with hydrocarbon solvents for PT 18 and 19	
The BPC postponed the adoption of the opinion on PT 18. The BPC adopted by consensus the opinion on the approval of the active substance for PT 19.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **28 January 2021.** **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 **22 December 2021** and publish them on the ECHA website.
7.6 Draft BPC opinion on Didecyldimethylammonium chloride (DDAC) for PT 1 and 2	
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 **28 January 2021.** **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 **22 December 2021** and publish them on the ECHA website.
7.7 Revised Assessment Report following the submission of data after active substance approval:	
7.7.1 Permethrin	
The member from NL informed the BPC about the evaluation of the data submitted after the approval. The evaluation was agreed upon.	**Member (NL):** to forward the revised assessment report with the List of Endpoints to the SECR by **15 December 2021.**
7.7.2 Transfluthrin for PT 18	
The member from NL informed the BPC about the evaluation of the data submitted after the approval. The evaluation was agreed upon.	**Member (NL):** to forward the revised assessment report with the List of Endpoints to the SECR by **15 December 2021.**
7.7.3 Chlorocresol	
The member from NL informed the BPC about the evaluation of the data submitted after the approval. The evaluation was agreed upon.	**Member (NL):** to forward the revised assessment report with the List of Endpoints to the SECR by **15 December 2021.**
Item 8 – Union authorisation	
8.1 Draft BPC opinion on an Union authorisation application for a biocidal product family containing hydrogen peroxide	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **15 December 2021.**

	SECR: to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **22 December 2021** and publish them on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **28 January 2021**.
8.3 Draft BPC opinion on an Union authorisation application for a biocidal product family containing L-(+)-lactic acid	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **15 December 2021.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **22 December 2021** and publish them on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **28 January 2021**.
Item 9 – Article 75(1)(g) opinion requests	
9.1. Draft BPC opinion on evaluation of the level of the risks for human health and for the environment of DBNPA used in biocidal products of product type 4	
The BPC adopted by majority the opinion.	**Rapporteur:** to revise the assessment report - including the underlying report - in accordance with the discussions in the BPC and submit to the SECR by **15 December 2021.** **Members (SE & DE):** to submit the minority position by **10 December 2021** **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 **22 December 2021** and publish it on the ECHA website.
9.2 Draft BPC opinion on evaluation of the level of the risks for human health and for the environment of cyanamide used in biocidal products of product types 3 and 18	
The BPC adopted by majority the opinions for PT 3 and PT 18.	**Rapporteur:** to revise the assessment report - including the underlying report - in accordance with the discussions in the BPC and submit to the SECR by **15 December 2021.** **Member (DK):** to submit the minority position by **10 December 2021** for PT 3 and PT 18.

	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 **22 December 2021** and publish them on the ECHA website.
9.3 Draft BPC opinion on eligibility of peanut butter active substance for inclusion into Annex I to the BPR	
The BPC adopted by consensus the opinion.	**SECR:** to revise the draft opinion in accordance with the discussions. **SECR:** to forward the adopted opinion to COM by **22 December 2021** and publish it on the ECHA website.
9.4 Draft BPC opinion on Questions relating to a guidance on rodent traps developed by the German Environment Agency	
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 **22 December 2021** and publish it on the ECHA website.
Item 10 – Any other business	

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Part III - List of Attendees

Members	Advisors
BALDASSARRI Lucilla (IT)	ASK BJÖRNBERG Karolin (SE)
BORGES Teresa (PT)	CANO David (ES)
BROVKINA Julija (LV)	CATALDI Lucilla (IT)
CARBERRY Stephen (IE)	CHMELIKOVA Jana (SK)
CEBASEK Petra (SI)	DE LA FLOR Ignacio (ES)
CHEZEAU Aurelie (FR)	DE LA USADA Eduardo (ES)
DRAGOIU Simona (RO)	EHNI Markus (DE)
GONZALEZ MARQUEZ Maria Luisa (ES)	FUERTES Pedro (ES)
GREGERSEN Nina Falk (DK)	GEDUHN Anke (DE)
HADJIGEORGIOU Andreas (CY)	GKILPATHI Dimitra (GR)
HAHLBECK Edda (SE)	HOLTHENRICH Dagmar (DE)
HAKAITE Palmira (LT)	HÄMÄLAINEN Anna-Maija (FI)
JAGER Stefanie (DE)	JENSEN Stine (DK)
JARRETY Helene (BE)	KALKERS Lucas (NL)
JOHN Nina (AT)	KEHRER-BERGER Anja (DE)
KOIVISTO Sanna (FI)	KRAFTE Kristine (LV)
LANS Martine (NL)	KRUIDHOF Sabine (NL)
MIKOLAS Jan (CZ)	MUEHLE Ulrike (DE)
MIKOLASKOVA Denisa (SK)	MUIJS Barry (NL)
RANDALL Marit (NO)	NOORLOOS Brigitte (NL)
RZODECZKO Helena (PL)	PEELMAN Natania (BE)
SZENTGYORGYI Timea (HU)	PORTELA Cristina (ES)
VAGIAS Vasileios (EL)	RUDZOK Susanne (DE)
VRHOVAC FILIPOVIC Ivana (HR)	RUIZ LOPEZ Elena Fuensanta (ES)
ZIGRAND Jeff (LU)	SCHMOLZ Erik (DE)
Alternate members	SCHNEIDER Heiko (DE)
COLLET Romy (FR)	SKULTETYOVA Maria (SK)
ENSCH Svenja (LU)	VAN DEN BERG Suzanne (NL)
MALLIA Lothar Paul (MT)	WEINHEIMER Viola (DE
PYTHON Fracois (CH)	**European Commission**
RIFFAUT Léa (FR)	CAINZOS Garcia Marta (DG SANTE)
SULG Helen (EE)	CHATELIN Ludovic (DG SANTE)

DELVAUX Vincent (DG SANTE)	D'AGOSTINI Valeria
Accredited Stakeholder Observers	ESTEVAN MARTINEZ Carmen
BARBU Luminita	GUTIERREZ ALONSO Simon
DREVE Simina	HONKA Anni
GARMENDIA Irantzu	KREBS Bernhard
MIHAI Camelia	LAITINEN Jaana
VAN BERLO Boris	LIPKOVA Adriana
WEISS Aharon	MOTTET Denis
Applicants	MUELLER Gesine
Alzchem Trostberg GmbH	NICOL Annaig
Bayer	PAPADAKI Paschalina
CID LINES	RAULIO Mari
Contec Cleanroom (UK)	RUGGERI Laura
EQC consortium	SAEZ RIBAS Monica
EurO3zon	SCHIMMELPFENNIG Heike
Natural Pyrethrum task force/MGK	STASKO Jolanta
Natural Pyrethrum task force/Sumitomo	SZYMANKIEWICZ Katarzyna
Nutrition & Biosciences	UPHOF Andreas
SC Johnson	VALKOVICOVA Eva
Toxmind	VAN DER LINDEN Sander
US-ISC consortium	VAN DE PLASSCHE Erik
ECHA Staff	VAN GALEN Joost
AIRAKSINEN Antero	VANGHEEL Matthew
CARLON Claudio	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-41

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-41 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2.	BPC-A-41-2021_rev1	Draft agenda	
4.	BPC-M-40-2021	Draft minutes from BPC-40 Draft minutes from BPC-40_non-conf	
5.1	-	Administrative issues and report from the other Committees	
5.2	Presentation	Experience in using the Interact Collaboration Tool	
6.1	BPC-41-2021-01 BPC-41-2021-02 BPC-41-2021-03 BPC-41-2021-04	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	
7.1	BPC-41-2021-05	7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval	
7.7	BPC-41-2021-24A	7.7.1. Permethrin (NL)	Assessment report
	BPC-41-2021-24B		CAR
	BPC-41-2021-24C		Cover letter
	BPC-41-2021-24D		Doc_IIIA-A7
	BPC-41-2021-25A	7.7.2. Transfluthrin for PT 18 (NL)	Assessment report
	BPC-41-2021-25B		Document II
	BPC-41-2021-25C		Cover letter
	BPC-41-2021-26A	7.7.3. Chlorocresol (NL)	Assessment report
	BPC-41-2021-26B		CAR
	BPC-41-2021-26C		Cover letter
	BPC-41-2021-26D		Earth worms
	BPC-41-2021-26E		Terrestrial plants
9.		Any other business	

Substance documents				
Agenda Point	**Number**	**Substance-PT**	**eCA**	**Title**
7.2	BPC-41-2021-06A	Ozone PT 2	DE	Draft BPC opinion
	BPC-41-2021-06B-09B			Assessment report
	BPC-41-2021-06C			Open issues

	BPC-41-2021-07A	Ozone PT 4		Draft BPC opinion
	BPC-41-2021-07B			Assessment report
	BPC-41-2021-07C			Open issues
	BPC-41-2021-08A	Ozone PT 5		Draft BPC opinion
	BPC-41-2021-08B			Assessment report
	BPC-41-2021-08C			Open issues
	BPC-41-2021-09A	Ozone PT 11		Draft BPC opinion
	BPC-41-2021-09B			Assessment report
	BPC-41-2021-09C			Open issues
7.3	BPC-41-2021-10A	ADBAC/BKC PT 1	IT	Draft BPC opinion
	BPC-41-2021-10B			Assessment report
	BPC-41-2021-10C			Open issues
	BPC-41-2021-10D			Results summed tonnages
	BPC-41-2021-10E&16E_room_doc_1			Room document 1
	BPC-41-2021-10F&16F_room_doc_2			Room document 2
	BPC-41-2021-11A	ADBAC/BKC PT 2		Draft BPC opinion
	BPC-41-2021-11B			Assessment report
	BPC-41-2021-11C			Open issues
	BPC-41-2021-11D			Results summed tonnages
7.4	BPC-41-2021-12A	Chrysanthemum supercritical PT 18	ES	Draft BPC opinion
	BPC-41-2021-12B			Assessment report
	BPC-41-2021-12C			Open issues
	BPC-41-2021-12D			Appsources PP
	BPC-41-2021-13A	Chrysanthemum supercritical PT 19		Draft BPC opinion
	BPC-41-2021-13B			Assessment report
	BPC-41-2021-13C			Open issues
7.5	BPC-41-2021-14A	Chrysanthemum hydrocarbon PT 18	ES	Draft BPC opinion
	BPC-41-2021-14B			Assessment report
	BPC-41-2021-14C			Open issues
	BPC-41-2021-14D			Appsources PP
	BPC-41-2021-14E			Ref. specs.
	BPC-41-2021-15A	Chrysanthemum hydrocarbon PT 19		Draft BPC opinion
	BPC-41-2021-15B			Assessment report
	BPC-41-2021-15C			Open issues
7.6	BPC-41-2021-16A		IT	Draft BPC opinion

	BPC-41-2021-16B	DDAC PT 1		Assessment report
	BPC-41-2021-16C			Open issues
	BPC-41-2021-16D			Results summed tonnages
	BPC-41-2021-17A	DDAC PT 2		Draft BPC opinion
	BPC-41-2021-17B			Assessment report
	BPC-41-2021-17C			Open issues
	BPC-41-2021-17D			Results summed tonnages
8.1	BPC-41-2021-18A	UA: hydrogen peroxide	SI	Draft BPC opinion
	BPC-41-2021-18B			SPC
	BPC-41-2021-18C			PAR
	BPC-41-2021-18C1			PAR Conf annex
	BPC-41-2021-18C2			PAR MS Conf annex
	BPC-41-2021-18D			Open issues
8.2	BPC-41-2021-19A	UA: L-(+)-lactic acid	BE	Draft BPC opinion
	BPC-41-2021-19B			SPC
	BPC-41-2021-19C			PAR
	BPC-41-2021-19C1			PAR Conf annex
	BPC-41-2021-19D			Open issues
9.1	BPC-41-2021-20A	Art. 75(1)(g) DBNPA PT 4	DK	Draft BPC opinion
	BPC-41-2021-20B			Addendum assessment report
	BPC-41-2021-20C			Open issues
9.2	BPC-41-2021-21A	Art. 75(1)(g) Cyanamide PT 3	DE	Draft BPC opinion
	BPC-41-2021-21B & 22B			assessment report
	BPC-41-2021-21C			Open issues
	BPC-41-2021-22A	Art. 75(1)(g) Cyanamide PT 18		Draft BPC opinion
	BPC-41-2021-22B			assessment report
	BPC-41-2021-22C			Open issues
9.3	BPC-41-2021-23A	Art. 75(1)(g) peanut butter	ECHA	Draft BPC opinion
	BPC-41-2021-23B			Open issues
9.4	BPC-41-2021-24A	Art. 75(1)(g) Rodent traps		Draft BPC opinion
	BPC-41-2021-24B			Open issues

19 November 2021
BPC-A-41-2021_rev1

Draft agenda

41st meeting of the Biocidal Products Committee (BPC)

29 November – 3 December 2021

Meeting is held virtually via WebEx

Starts on 29 November at 10:30, ends on 3 December at 18:00

The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-41-2021_rev1

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-40

BPC-M-40-2021

For agreement

5. – Administrative issues

5.1. Administrative issues

For information

5.2. Experience in using the Interact Collaboration Tool

For discussion

6. – Work programme for BPC

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

BPC-41-2021-01; BPC-41-2021-02; BPC-41-2021-03; BPC-41-2021-04

For information

6.2. Update on active substance approval and Union authorisation

For information

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

7.1. Procedural and administrative aspects:

7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval

BPC-41-2021-05

For information

7.2. Draft BPC opinion on Ozone generated from oxygen for PT 2, 4, 5 and 11

Previous discussion: WG-III-2021

PT 2: BPC-41-2021-06A, B, C
PT 4: BPC-41-2021-07A, B, C
PT 5: BPC-41-2021-08A, B, C
PT 11: BPC-41-2021-09A, B, C

For adoption

7.3. Draft BPC opinion on Alkyl (C_{12-16}) dimethylbenzylammonium chloride (C_{12-16}-ADBAC/BKC) for PT 1 and 2

Previous discussion: WG-III-2021

PT 1: BPC-41-2021-10A, B, C, D
PT 2: BPC-41-2021-11A, B, C, D

For adoption

7.4. Draft BPC opinion on Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with supercritical carbon dioxide for PT 18 and 19

Previous discussion: WG-III-2021

PT 18: BPC-41-2021-12A, B, C, D
PT 19: BPC-41-2021-13A, B, C

For adoption

7.5. Draft BPC opinion on Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with hydrocarbon solvents for PT 18 and 19

Previous discussion: WG-III-2021

PT 18: BPC-41-2021-14A, B, C, D, E
PT 19: BPC-41-2021-15A, B, C

For adoption

7.6. Draft BPC opinion on Didecyldimethylammonium chloride (DDAC) for PT 1 and 2

Previous discussion: WG-III-2021

PT 1: BPC-41-2021-16A, B, C, D
PT 2: BPC-41-2021-17A, B, C, D

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).

7.7. Revised Assessment Report following the submission of data after active substance approval:

7.7.1. Permethrin

BPC-41-2021-24A, B, C, D

For agreement

7.7.2. Transfluthrin for PT 18

BPC-41-2021-25A, B, C

For agreement

7.7.3 Chlorocresol

BPC-41-2021-26A, B, C, D, E

For agreement

8. – Union authorisation**

8.1. Draft BPC opinion on an Union authorisation application for a biocidal product family containing hydrogen peroxide

Previous discussion: WG-III-2021

BPC-41-2021-18A, B, C, D

For adoption

8.2. Draft BPC opinion on an Union authorisation application for a biocidal product family containing L-(+)-lactic acid

Previous discussion: WG-III-2021

BPC-41-2021-19A, B, C, D

For adoption

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

9.1. Draft BPC opinion on evaluation of the level of the risks for human health and for the environment of DBNPA used in biocidal products of product type 4

Previous discussions: WG-II-2021 & WG-III-2021

BPC-41-2021-20A, B, C

For adoption

9.2. Draft BPC opinion on evaluation of the level of the risks for human health and for the environment of cyanamide used in biocidal products of product types 3 and 18

Previous discussions: WG-II-2021 & WG-III-2021

PT 3: BPC-41-2021-21 A, B, C

PT 18: BPC-41-2021-21 A, B, C

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 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).

9.3. Draft BPC opinion on eligibility of peanut butter active substance for inclusion into Annex I to the BPR

BPC-41-2021-22 A, B

For adoption

9.4. Draft BPC opinion on questions relating to a guidance on rodent traps developed by the German Environment Agency

BPC-41-2021-23 A, B

For adoption

10.- Any other business

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11.– Action points and conclusions

Provisional time schedule for the

41st meeting of the Biocidal Products Committee (BPC)

Virtual meeting via WebEx

29 November 2021: starts at 10:30; 3 December 2021 ends at 18:00

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.

Monday 29 November: (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	Procedural and administrative aspects:
	7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval
Item 8.1	Draft BPC opinion on an Union authorisation application for a biocidal product family containing hydrogen peroxide for PT 2 (BC-PP063133-29), eCA SI
Item 8.2	Draft BPC opinion on an Union authorisation application for a biocidal product family containing L-(+)-lactic acid for PTs 1, 2, 3, 4 (BC-RC051007-54), eCA BE

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

Item 9.1	Draft BPC opinion on evaluation of the level of the risks for human health and for the environment of DBNPA used in biocidal products of product type 4
Item 9.2	Draft BPC opinion on evaluation of the level of the risks for human health and for the environment of cyanamide used in biocidal products of product types 3 and 18

Wednesday 1 December: (starts at 10:30 EET / 09:30 CET, ends at 18:00 EET / 17:00 CET)

Item 7.2	Draft BPC opinion on Ozone generated from oxygen for PT 2, 4, 5 and 11
Item 9.3	Draft BPC opinion on eligibility of peanut butter active substance for inclusion into Annex I to the BPR
Item 9.4	Draft BPC opinion on questions relating to a guidance on rodent traps developed by the German Environment Agency

Thursday 2 December: (starts at 10:30 EET / 09:30 CET, ends at 18:00 EET / 17:00 CET)

Item 7.3	Draft BPC opinion on Alkyl (C12-16) dimethylbenzylammonium chloride (C12-16-ADBAC/BKC) for PT 1 and 2
Item 7.6	Draft BPC opinion on Didecyldimethylammonium chloride (DDAC) for PT 1 and 2
Item 7.7	Revised Assessment Report following the submission of data after active substance approval:
	7.7.1 Permethrin
	7.7.2 Transfluthrin for PT 18

7.7.3 Chlorocresol

Friday 3 December: (starts at 10:30 EET / 09:30 CET, ends at 18:00 EET / 17:00 CET)

Item 7.4	Draft BPC opinion on Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with supercritical carbon dioxide for PT 18 and 19
Item 7.5	Draft BPC opinion on Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with hydrocarbon solvents for PT 18 and 19
Item 10	Any other business
Item 11	Action points and conclusions

End of meeting

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