18 January 2022

BPC-M-40-2021

Minutes of the 40th meeting of the Biocidal Products Committee (BPC)

5-7 and 12-14 October 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 40th BPC meeting which took place as a virtual meeting via Webex.

The Chair then informed the BPC members of the participation of 27 members, including one alternate member.

42 Advisers (of whom 6 in double role also as an alternate member) and 7 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 and biocidal products under agenda item 8, 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-40-2021_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-39

The revised draft minutes from BPC-39 (BPC-M-39-2021), incorporating the comments received, were agreed.

The Chair mentioned that all actions from the previous BPC-39 meeting were carried out:

Actions:

- **SECR:** to upload the agreed minutes from BPC-39 to the BPC S-CIRCABC IG and to the ECHA website after the meeting.

5. Administrative issues

5.1 Administrative issues

The Chair informed that BPC-41 will be one week virtual meeting.

5.2 Experience in using Interact Collaboration Tool

The SECR gave a short presentation on recent experiences and future directions in using Interact Collaboration Tool. As a solution for the encountered problems SECR will at least onboard more users and a different template for commenting will be explored.

The members had mixed feelings with regards to the Collaboration tool. Several members indicated that they are positive about the tool while others supported the concept but at the same time saw several items that need to be improved. For some members the collaboration tool doesn't suit the way their organisation works as it takes for their Member State more time to draft and submit comments in the Interact Collaboration Tool compared to the previous process where comments were submitted via S-CIRCA BC.

Several members mentioned that it was useful to see the comments made by other members states, contrary to that several members mentioned that they didn't have time to consider the comments made by others.

Improvements that were mentioned by the members included:

- the document structure doesn't allow copy pasting;
- more users need to be onboarded;
- contact details should be added to collaboration documents so that participants can notify eachother;
- create a lists of users that have access to the Interact Collaboration;
- process for freezing of collaborations needs to be improved;
- notifications for significant changes in collaboration documents;
- download of all documents in a collaboration in one action.

Actions for SECR:

- To publish the presentations on the BPC S-CIRCABC IG;
- Provide information on how to onboard new users;
- Create a document with some practicalities on how to use the collaboration functionality. At the same time the collaboration documents should become easier to use.

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 by **22 October 2021** 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 AS – Review Programme from 15 to 16. Sulfur dioxide had to be postponed to BPC-42 as the RAC did not conclude on the classification at their last meeting.
- For 2022 an increase is still expected however for both AS and UA. The Chair referred to the presentation under agenda item 8.1 which informed on both AS and UA future submissions and to discussions at the last CA meeting where ECHA also reported on the forecasting for AS and UA.
- Four opinions following an Article 75(1)(g) request are now scheduled for 2021: one more was received (on Annex I inclusion of peanut butter) which is on the agenda of this meeting.
- The Chair referred to the status of ED assessment for information purposes and mention that the changes compared to the overview presented for BPC-39 is highlighted in bold: MBO and HPT will be discussed at BPC-43.

The Chair asked the eCAs being rapporteur for active substances or Union authorisations scheduled for discussion at the November/December 2021 BPC meeting (BPC-41), to confirm this planning to the SECR by 22 October 2021.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by 22 October.

6.2 Meeting the timelines: alternative ways of working

The SECR gave a presentation on "Meeting the timelines: alternatives ways of working. Progress and status". This presentation gave an overview on the feedback received after BPC-39 on the two main actions taken up from the MSs workshop on adjusting the ways of working. These proposals consider the challenges of meeting the peer-review timelines with the current limitations on resources and increase of workload on the active substance approval and Union authorisation process:

- The concept of co-rapporteurship for the peer-review and the feedback from the Working Groups (WGs) was presented. The BPC confirmed the main issues already raised by WG members, being less harmonisation in evaluation and difficulties to ensure that all dossiers are evaluated in same way, loss of transparency in decisions on technical level and reduced diversity of opinions. The BPC therefore agreed not to follow up the co-rapporteurship further.

  The alternative proposals provided by BPC members will be followed up internally at SECR. The proposal to send finalised parts of the CAR (Competent Authority Report) to Working Groups upfront, since the ED assessment is delaying the evaluation, was specifically discussed and the proposal was supported by two other BPC members.

Action: **SECR** to follow up alternative proposals, including the proposal to sending finalised parts of the CAR to Working Groups upfront.

- Based on the feedback from MSs, it was proposed to maintain adhoc follow-ups (AHFUs) only in exceptional situations. SECR presented the criteria for organising an AHFU. SECR concurred with MSs that defining the criteria for AHFUs will help to restrict its use to situations where it is really necessary and SECR noted that this proposal is aligned with the current practice where AHFUs have already been reduced. The BPC agreed with the SECR proposal.

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-39.

Actions:

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

7.2. Draft BPC opinion on BIT for PT 6 and 13

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

The rapporteur briefly introduced the cases of 1,2-Benzisothiazolin-3-one (BIT) which are backlog dossiers for PT 6 and 13. The chair informed that several late documents were made available: i) one from the Applicant on additional information on effectiveness of some proposed risk management measures (RMMs); ii) a proposal from one of the members on possible restrictions for treated articles for PT 6; iii) a reaction from the Applicant on this proposal.

Assessment report (AR):

The BPC went through all points as presented in the open issue table. Below are highlighted the more critical issues.

Risk characterisation ratio (RCR): when the RCR is > 1 an unacceptable risk is identified. The applicant was arguing that the result cannot be expressed in a higher degree of prescriptiveness (two digits after the decimal point) than the actual value requires. The BPC members were of the opinion that the regulatory cut-off is set to 1 and therefore a risk was identified. The SECR will further reflect on this issue.

Proposal on restrictions for treated articles for PT 6: one member highlighted that the assessment shows unacceptable risks to the environment and/or human health for several uses. The approval for the substance is proposed with the justification that one safe use has been shown. For the uses showing unacceptable risk, a refinement of the assessment

is proposed to be postponed to the product authorisation stage. The member argued against this proposal for the following reasons: i) it is not possible to postpone the risk assessment of non-acceptable uses in treated articles to the product authorisation stage since restrictions on the placing on the market of treated articles cannot be introduced at product authorisation, unless stipulated in the approval decision for the active substance1; ii) the import of treated articles is not possible to control – irrespective whether risks are known or not – unless a restriction for placing on the market has been stipulated in the approval decision, since product authorisation will not take place for imported treated articles. Therefore the members proposed to introduce a positive listing of the use in those treated articles for which no unacceptable risk is identified. This proposal was also presented at the CA meeting in 28-29 September 2021, where it was concluded by the Commission that such an approach may be considered by the BPC but without leading to delays for the active substances evaluated under the Review Programme. The Commission representative informed the BPC meeting that a standard sentence for a condition at approval stage, which will enable the introduction of risk mitigation possibilities for treated articles at product authorisation, is under preparation, and discussions are still on-going with Member States at the CA meeting level. The applicant argued against the proposal: i) adopting the approach would lead to a commercial disadvantage for the applicants for BIT as this would be "ad-hoc" agreed for BIT whereas this has not been applied for previous active substance in a similar situation; ii) predictability of procedure and rules are up most important for industry and would not be adhered to in this case: the assessment of BIT is done based on an old guidance – dossiers were submitted more than 10 years ago; iii) the applicant should therefore be given the opportunity to submit additional information.

One member expressed agreement with the proposal, especially for BIT as there unacceptable risks linked to the use in treated articles (for human health and for environment – even more compartments). The member expressed their concern on the risk management measures proposed with respect to their applicability. Other members supported the proposal but stated that it can only be taken into account in the future as there are still many open issues such as: i) legal concerns raised at the CA meeting indicated above; ii) lack of guidance on how to define the use categories as suggested in the proposal; iii) clarification is needed on whether the applicant can submit additional information. The member suggested to await implementation to the renewal process. For the moment one representative safe use is enough for active substance approval. It was argued that according to the BPR it must be shown that one representative product is safe and not that there needs to be one safe use of a biocidal product.

Several other members also agreed on the importance of this topic, but expressed it is too early to implement it. It was suggested to discuss the concept of use categories with the sub-group on the BPR of the Forum. It was also suggested that the BPC should receive a mandate to further develop the proposal.

The Chair concluded that even though there was overall sympathy for the proposal, the majority of the members considered it premature to implement it for BIT for PT 6.

[1] The current views of the Commission services are that clarifying/setting risk mitigation measures for treated articles at product authorisation is only possible if such a condition is set at the active substance approval (CA-June21-Doc.4.2.b - Note for the CA on labelling treated articles).

Opinion for PT 6:

It was discussed that it is very important to state in the BPC opinion for every use of the biocidal product in a treated article (for example paints, detergents, preservation of glues and adhesives) assessed whether the risk is acceptable and whether the introduction of risk management measures (RMM) can mitigate the risk to acceptable levels.

For the risk assessment for human health – for which only the use in detergents and paints and coatings was assessed - it was agreed that RMM for medium hazard chemicals shall be specified. For "mixing and loading – hand washing laundry" for non-professionals – the RMM shall be changed to "packaging minimising exposure". In addition, it was agreed that the proposed RMMs (labelling, instructions for use, childproof closure, packaging eliminating exposure) for the use in paints for non-professionals are not feasible. Instead it was agreed to introduce a condition that the concentration of BIT shall be below the concentration triggering classification as a skin sensitiser.

For the risk assessment for the environment it was agreed that more information and details need to added to the overview presented in the opinion: a distinction must be made between service life, application and formulation of for example the paint and to indicate whether the risk is acceptable for each compartments. In addition, the possibility of mitigating unacceptable risks via the introduction of RMMs should be indicated. However, it was agreed that the outcome of the risk assessment for the scenarios described in the opinion will not change. Overall this means that there are several scenarios for which an unacceptable risk is identified (for example for preservation of additives used in paper production), but that there are scenarios with acceptable risks for all compartments (for example for preservation of detergents and cleaning fluids). The latter enables a proposal to approve BIT in PT 6 as a safe use is identified for the environment as well as for human health.

Several RMMs were presented in the opinion as well as options to refine the risk assessment by submitting additional information during product authorisation such as stability studies of BIT in preserved products, leaching studies and monitoring data. With respect to the RMMs it was agreed that no conclusion can be drawn at this stage on their effectiveness. One member emphasised that the proposals are refinements of the evaluation and cannot be considered RMMs. This would subsequently need to be demonstrated at product authorisation. Some proposed RMMs were discussed and it was agreed to amend or remove some. For example it was agreed – in line with other opinions - that it is not possible to request on-site RMMs for preserved pulp and paper processing fluids as such measure would not be under the control of the authorisation holder.

The Commission highlighted that the opinion shall also clearly mention which uses applied for were assessed and which not, noting that several uses seem to be assessed for their environmental risks but not for their risks to human health, which is not the normal practice. In addition, it was stated that if RMM are not introduced as a condition for the placing on the market of treated articles in the opinion, it will not be possible to introduce them later at product authorisation stage. This was discussed by the committee but it was argued that it is not possible to foresee at this stage – i.e. active substance approval stage – what measures would be required at product authorisation.

It was confirmed that as a conclusion on ED properties with respect to humans was made, BIT does not fulfil criterion (d) of Article 5(1).

The BPC was informed that there is a CLH dossier submitted for BIT with a proposed classification as Skin Sens 1B and a specific concentration limit which is different from

other isothiazolinones. The SECR informed that BIT is planned to be discussed still this year in RAC-59.

All issues indicated in the open issues table were discussed and agreed. The assessment report was agreed, and the BPC opinion was adopted by majority. The member from SE provided a minority position.

Opinion PT 13:

It was agreed that in the scenarios “automatic loading” and “handling of work pieces, tools outside the turning machine” to enable a safe use the requirement “new gloves for each work shift” has to be added. In addition, it was agreed – in line with other opinions for PT 13 - to remove the requirement to use gloves from the scenario “metal working fluids on turning machine” as the use of gloves near rotating machinery is considered to be a safety hazard which should be avoided.

It was clarified that even though unacceptable risks are identified for the environment, risk management measures are available to treat the water phase which lead to sufficiently lower concentrations of BIT to avoid such risks. The applicant provided additional information showing that chemical oxidation significantly reduces the concentration of BIT. One member (FR) noted that these results were variable and not always demonstrating a significant reduction of concentration of BIT. It was agreed that the measures described in the opinion are feasible, however at product authorisation information may need to be submitted to demonstrate that there are no unacceptable risks. It was decided to include an element to be taken into account when authorising products requiring that treatments of the water phase should achieve a reduction of the concentration of BIT by at least 85%.

All issues indicated in the open issues table were discussed and agreed. The Assessment Report was agreed and the opinion for PT 13 was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 26 November 2021.
- Member (SE): to submit the minority position on PT 6 by 21 October 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 5 November 2021 and publish it on the ECHA website.

7.3. Draft BPC opinion on d-Allethrin for PT 18

The Chair welcomed the applicant. The ASOs were not allowed to be present during the discussion.The repporteur introduced briefly the dossier. All points related to the Assessment Report and BPC opinion, indicated in the open issues table, were addressed by the Committee. The opinion was adopted by majority. A minority opinion will be filed by the CZ member.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 26 November 2021.
- **Member (CZ)**: to submit the minority position by 21 October 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 5 November 2021 and publish it on the ECHA website.

7.4. Article 75(1)(g) request on "Eligibility of peanut butter active substance for inclusion into Annex I to the BPR"

The Chair informed the meeting that ECHA has received this request from the Commission for an Article 75(1)(g) opinion. The Chair informed that ECHA will act as the rapporteur and the BPC opinion has to be delivered to the COM by 31 January 2022. The BPC agreed with appointing ECHA as the rapporteur.

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

7.5.1. Permethrin for PT 8 and 18

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

The involved evaluating CA Ireland informed the meeting that they accepted the post approval data submitted by the applicant and responded to the comments made by the BPC members.

The revised Assessment Report was agreed by the meeting. This means that permethrin meets the T and the P criterion and subsequently it meets the conditions of Article 10(1)(d) and comparative assessment is needed for products containing permethrin. Furthermore it was concluded that a statement will be included in the Assessment Report that data to conclude on the B criterion has to be submitted for renewal.

Actions:

- **Member (IE):** to forward the revised assessment report with the List of Endpoints to the SECR by **5 November 2021.**

7.5.2. OIT for PT 8

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

The involved evaluating CA France informed the meeting that the post approval data for the environment were submitted by the applicant and accepted by the UK (the eCA of OIT

before Brexit and the takeover of the active substance assessment by France). . The confirmatory methods of analysis for the determination of OIT in soil and water and accuracy data required for method of analysis for the determination of OIT in technical material (which were part of the BPC opinion 2.5 requests) will be requested in the evaluation of the other product types (PTs) of OIT performed by France.

The evaluation performed and the updated Assessment Report was agreed by the meeting. This means that the status of OIT with respect to its PBT and vPvB properties (as laid down in the BPC opinion adopted in 2016) was confirmed: OIT is “not P or vP” and is also “not B or vB”.

Actions:

- **Member (FR):** to forward the revised assessment report with the List of Endpoints to the SECR by **5 November 2021.**

7.6. Article 15(2) request on the review of approval of the active substances iodine, polyvinylpyrrolidone iodine and zineb: rapporteurship for iodine and polyvinylpyrrolidone iodine

The Chair informed the meeting that ECHA has received this request from the Commission for an Article 15(2) opinion. The Chair informed that Sweden volunteered to act as the rapporteur for iodine and polyvinylpyrrolidone iodine. The BPC agreed with appointing Sweden as the rapporteur for these active substances.

8. Union authorisation

8.1 Update on 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) accordance check for AS and UA, ii) derogations for UA; 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 noted that the cases planned to enter peer-review during Q2 and the first half of 2023 will increase significantly. The BPC members commented on the figures and made proposals on the management of these high numbers in peer-review. SECR mentioned that the recent change of timelines was due to adjustment in the duration of BPC meetings. SECR is aware of impact of this change in the organisation of MSs work and for next timelines the new 2-week BPC meeting scheme will be taken into account from the beginning. MSs indicated their limits to provide comments to all the dossiers coming to BPC meeting.

ii) Accordance check for AS and UA

SECR informed the BPC about the revision of the extended accordance check and the practice of sharing the results of the extended accordance check with the eCAs, independently of the outcome of the accordance check. A BPC member indicated

the impact of a failure in the accordance check in the planning and resources at CA level. The COM invited ECHA to reflect internally on the accordance check considering that this step is not foreseen in the BPR and in some cases it creates confusion about the status of the dossier. SECR informed that the accordance check step is agreed by the MSs and is included in the relevant working procedures. In addition, the current practice is to contact the eCA during the accordance check when critical issues are identified with the intention to solve these, where possible, during the peer-review and avoid blocking the dossier.

iii) Derogations

SECR asked the BPC whether MSs would be able to provide information on intentions for derogations based on Article 44(5) before the BPC meeting. On this point, the MSs will provide their feedback in writing.

On a more general note, the SECR reminded that from now on all communication in relation to UA process will be sent to all BPC members, i.e., the UA contact point e-mail list will not be in use anymore. In addition, the SECR asked eCAs and ASOs to remind the applicants to keep their contact details in R4BP3 up to date.

Actions:

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

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

The Chair welcomed the applicant. The ASOs were not allowed to be present during the discussion. The rapporteur briefly introduced the dossier. No comments were provided on the PAR or the confidential Annex of the PAR and also no comments were raised at the meeting. The documents were agreed.

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 29 October 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 5 November 2021 and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by 26 November 2021.

8.3. Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from sodium hypochlorite

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

PAR:

The proposal of the applicant to have for certain uses a separate claim for biofilms from the "mandatory organisms" was agreed. Reason for having the biofilm claim separate is that here the contact time is longer which means that the in-use concentration can be lower compared to the "mandatory organisms". Separation of the biofilm claim therefore prevents the risk of over dosing. It was also agreed that the organisms tested for demonstrating the efficacy for the biofilm claim need to be mentioned.

One member did not agree with the outcome of the qualitative risk assessment for coarse spraying as for a corrosive product they consider that exposure should be zero. The eCA explained that the measures proposed (full face mask with a P3 filter, gloves with the appropriate break through time in combination with the fact that it concerns directional spraying) were the outcome of the assessment and considered sufficient to mitigate the risks. It was argued by the member that discussion at the Working Group Human Health would be needed to discuss if further reduction of the exposure would be feasible with alternative measures. The Chair explained that in this procedure this was not possible as otherwise the 180 days timeline for the opinion would not be met. The eCA explained that there is no cloud formation as the spraying is directional. Several members supported the eCA. It was concluded to accept the outcome of the qualitative risk assessment as performed by the eCA.

SPC:

The BPC discussed – following a discussion at the Standing Committee for another application after the adoption of the opinion at the last meeting – how to present the composition of the biocidal product in section 2.1 of the SPC. This is a general issue relevant for all applications concerning biocidal products containing the following actives: i) active chlorine released from sodium hypochlorite; ii) active chlorine released from calcium hypochlorite iii) active chlorine released from hypochlorous acid; and iv) active chlorine released from chlorine.

It was concluded that the preferred approach is to present: i) the content of available active chlorine under the common name "Active chlorine released from [name releaser]", where the function is "Active substance" and no CAS and EC number is indicated (in order to make this possible ECHA indicated that the SPC Editor can be amended within a month of the end of the meeting[2]); ii) the content of the releaser (expressed as technical material) where the common name is the name of the releaser; the function is "Releaser" and the concerned CAS and EC number – if available – are indicated.

However, ECHA indicated that the SPC Editor needs to be amended to make it possible to list "Releaser" under the heading "Function", which may take several months. Before this change to the SPC Editor is implented, the "Function" can only be "Non-active substance".

[2] ECHA will also investigate if it possible with the current version of the SPC Editor to list all releasers concerned under the heading "Common name".

Under the assumption that ECHA will prioritise the change (so enabling to list “Releaser”) to the SPC Editor the meeting agreed to adopt this approach – meaning the “Function” for the releaser will be “Non-active substance”. It was agreed to use this approach not only for the relevant applications on the agenda for this meeting but also for the ones adopted at the last BPC meeting.

Some members argued that it is confusing for the user of the SPC to list “Non-active substance” for the releaser. However, it was argued by others that the two lines in this section should be read in conjunction where the line above states in fact that active chlorine is released from the concerned releaser, so it is clear that the function is not a “Non-active substance” comparable to other co-formulants (for example a colouring agent identified as a substance of concern). It was argued by several members that the chosen approach is in line with the CLP requirements as it lists the technical content of the releaser (which is also crucial information for enforcement authorities who do not need the content of active chlorine) and it is informative for the end-user (which can be also consumers) as the information on the active chlorine content is presented.

One member suggested to replace the measure “After disinfection by coarse spraying or foaming, the treated area can be re-entered only when an ambient air concentration of chlorine is ensured to be below 0,5 mg/m³.” by “general public should not enter just after the application by coarse spraying” under the assumption that no aerosols will remain in the air after spraying taking into account the contact time. Other members disagreed stating that a fraction of the aerosols formed will remain always in the air where in addition no measurements are available in the application. Therefore, the measure is needed to determine the time needed before re-entry is allowed. The applicant clarified that a technique to carry out such measurements is available and can be easily put in place. It was therefore agreed to keep the measure in the SPC.

Opinion:

It was agreed to add to the overview already present those uses which were present in the applicant but for which it was agreed not to grant the authorisation. For future opinions it was decided to have always a table presenting the authorised and not authorised uses, where there would be no need to repeat information under for example the section on efficacy and the overall conclusions. Also, there is no need for too much detail (here reference was made to information stemming from the evaluation of the efficacy for the different meta SPCs and uses); the outcome can be presented in terms of “acceptable” and “not acceptable”.For applications which are relatively straightforward (for example single products with a limited number of uses) such an overview will not be needed. The SECR will prepare a template for such a table.

The proposed post-authorisation data condition for the self-accelerating decomposition temperature (SADT test) was discussed. The eCA explained that this is a confirmatory test as it is considered that for the concerned meta-SPCs classification as a self-reactive substance or mixture is not required. Subsequently, the eCA considers that the conditions of Article 19(1)(d) of the BPR are met and these uses can be authorised. The meeting agreed with the eCA and asked to include this explanation in the opinion. The Commission stated they preferred to not have such conditions included in the opinion even if the applicant indicated that no change in classification would be expected. This will be further examined by the Commission.

The opinion was adopted by majority of the members having the right to vote. The member from FR submitted a minority opinion.

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 29 October 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 (FR): to submit the minority position by 21 October 2021.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by 5 November 2021 and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by 26 November 2021.

8.4 Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from calcium hypochlorite

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

There were limited comments on the draft PAR, SPC and BPC opinion. A clarification on the need to change the chemical name of a co-formulant in the confidential PAR was provided.

It was noted that further to the product classification as Skin Corr. 1, also Eye Dam. 1 classification should be added to the “Hazard Category” in the PAR and the opinion, where full product classification should be provided. However, in line with the CLP Regulation, the corresponding hazard statement H318 is not needed in the SPC and on the product label, as it is already covered by the hazard statement H314.

The proposed post-authorisation requirement for long-term storage stability test for Meta-SPC-4 was supported, following the eCA clarification on available storage stability data, on the currently set 12-month shelf-live and on possibilities for extension following the submission of a minor change application.

It was further noted that the name of the active substance in the SPC should be changed to ‘Active chlorine released from calcium hypochlorite’ while the substance identifiers and content listed should refer to the releaser (as a technical substance).

One member informed about a derogation request under BPR Article 44(5), due to exceedance of established national limits for drinking water disinfection and swimming pool waters. In this regard, the member posed a minority position.

All further items in the open issues table were addressed. The BPC opinion, the draft SPC and the PAR will be revised according to the conclusions reached at the BPC and as reflected in the open issue table.

The opinion was adopted by simple majority of the members present having the right to vote.

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 29 October 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 (DE)**: to submit the minority position by 21 October 2021.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by 5 November 2021 and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by 26 November 2021.

8.5 Draft BPC opinion on an Union authorisation application for a biocidal product containing propan-2-ol

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

All the identified open points were addressed and closed during the meeting. In particular it was agreed to amend the PAR and draft SPC in accordance with the items listed below:

For products intended for professional use, the sentence “Keep out of reach of children and pets” will remain under the heading Risk mitigation measures. The sentence “For professional use only” will be added under the heading “Field of use”.

For products intended for non professional use, the sentence “Keep out of reach of children and pets” will be placed under the heading “Conditions of storage”.

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 29 October 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 5 November 2021 and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by 26 November 2021.

8.6 Draft BPC opinion on an Union authorisation application for a biocidal product containing propan-1-ol and propan-2-ol

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

All the identified open points were addressed and closed during the meeting. In particular, it was agreed to maintain the risk mitigation measure “Keep out of reach of children” and to include the words “For professional use only” in the heading “Field of use” and in the “Instructions for use”.

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 29 October 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 5 November 2021 and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by 26 November 2021.

8.7 Draft BPC opinion on an Union authorisation application for a biocidal product containing propan-1-ol and propan-2-ol

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

All the identified open points were addressed and closed during the meeting. In particular, it was agreed to maintain the risk mitigation measure “Keep out of reach of children” and to include the words “For professional use only” in the field of use and in the “Instructions for use”.

Clarification was sought regarding the exposure of professional by-standers during disinfection of food processing industry and the limitation of the number of applications to 6 per day during the disinfection of small surfaces in medical, institutional and industrial premises. It was explained that the exposure of professional bystanders is covered by the scenario of professional users and that the limitation to 6 applications per day is due to the fact that a higher number of applications would lead to unacceptable risk.

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 29 October 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 5 November 2021 and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by 26 November 2021.

8.8 Draft BPC opinion on an Union authorisation application for a biocidal product containing hydrogen peroxide

The Chair welcomed the applicant. The stakeholders were allowed to be present during the discussion. The rapporteur briefly introduced the dossier. The family is composed of 15 product formulations divided in 9 Meta-SPCs for disinfection in PTs 2, 3 and 4. All uses are for professional use.

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

The approach taken on classification for physical and environmental hazards of the products in this family were explained to the applicant. It was also clarified that the MSCA from Finland is going to submit a CLH dossier for the active substance next year.

One member raised the issue with the parameters that should be mentioned in the SPC for the uses 1 (Surface disinfection of closed spaces by aerosolised hydrogen peroxide) and 9 (Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP)). The rapporteur clarified that these parameters are already stated in the use specific instructions for use in the sentence describing how efficacy can be attained. The member suggested some amendments to the statement in the SPC, i.e., to add the information that the bacterial spores were used to demonstrate the efficacy. The applicant confirmed that in practice there is normally on-site validation of the disinfection system and also constant monitoring of the efficacy for the applications such as described in uses #1 and #9.

The BPC opinion, the draft SPC and the PAR will be revised according to the conclusions reached at the BPC and as reflected in the open issue 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 29 October 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 5 November 2021 and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by 26 November 2021.

8.9 Draft BPC opinion on an Union authorisation application for a biocidal product containing hydrogen peroxide

The Chair welcomed the applicant for this item. The ASOs were not allowed to be present during the discussion. The rapporteur introduced briefly the dossier. All points related to the PAR, SPC and BPC opinion, indicated in the open issues table, were addressed by the Committee.

The BPC 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 29 October 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 5 November 2021 and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by 26 November 2021.

8.10 Draft BPC opinion on an Union authorisation application for a biocidal product containing cyromazine

The Chair welcomed the applicant and briefly reported on the discussion in the closed session informing that the current assessment would remain unchanged with respect to the metabolite melamine. The stakeholders were allowed to be present during the discussion. The rapporteur introduced briefly the dossier.

With respect to the metabolite melamine, DE pointed out that using the trigger value of 0.1 µg/L for groundwater assessment led to the situation that the number of applications of the products had to be reduced to a level where DE questions the reasonable use of the product. Additionally, this restriction does not prevent users applying another similar product with the same active substance. Furthermore, DE questions whether eCAs have to back-calculate until there is a safe use identified.

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The BPC opinion, the draft SPC and the PAR will be revised according to the conclusions reached at the BPC and as reflected in the open issue table.

The Applicant raised the issue of the outdoor uses for which efficacy was not demonstrated and therefore could not be considered in the assessment. The Applicant reported that a waiver for efficacy data for outdoor use had been applied during the evaluation and that at that stage the Applicant had informed that available studies could be made available. The waiver was considered not acceptable during the trilateral discussions, and the comment closed during trilateral discussions. This prevented the Applicant from submitting the additional data. The Applicant noted that applying for a major change to include outdoor uses once authorisation has been granted, is an administrative burden. However, one member noted that the studies submitted by the Applicant for the BPC were not considered sufficient to support a claim against outdoor flies. The Chair informed that the working procedures are being revised and the concerns raised by the Applicant will be addressed.

The procedural aspects of the reassessment of the PBT status of cyromazine were also discussed. Based on the toxicological relevance of the metabolite melamine and the new information available (a recent RAC opinion on the classification and labelling), the PBT status of cyromazine needs to be re-assessed. It was discussed that as cyromazine meets the P criterion, if it is confirmed that the T criterion is also fulfilled due to the RAC opinion for melamine, the active substance will be considered a candidate for substitution. The Chair concluded that the PBT status should be clarified at BPC level and that the SECR will

prepare a discussion paper on this for the BPC-41. Furthermore, in case cyromazine is confirmed to be a candidate for substitution, the eCA will need to perform a comparative assessment. The Commission informed that until this process is concluded they will not be able to take a decision regarding the authorisation of Hokoex as new information of this nature (here that an active substance now meets the conditions for being a candidate for substitution) arriving before an authorisation decision is issued cannot be ignored, and it will likely have to send back the opinion to ECHA.

SE informed the BPC members about the potential request to the Commission to adjust the conditions for use on the Swedish market by only including professional use. CH agreed to remove the instruction for use "Use only in housing of animals not destined for food production" from the SPC for use #2 (non-professional users). SE indicated to have other concerns and would need to reassess whether to submit the derogation.

There was also some debate concerning the proposed sentence in the SPC "Inform the authorisation holder if the treatment is ineffective". The question on whether to remove the sentence was raised, referring to a recent discussion at the Standing Committee (SC) level. One member reported that it has been agreed at SC level to remove any sentences referring that ECHA or the eCA have to be informed by the user, which is not the case here. In addition, the current sentence is often used in national authorisations. Therefore, the member argued there is no reason to remove the sentence. The Chair argued that the sentence could be removed as it concerns a general obligation under the BPR, so it can be considered as redundant. The Chair concluded that the sentence will remain in the SPC. The Commission confirmed to look into the past SC discussions.

The Chair – following a questions by one of the members - clarified why a conclusion regarding the endocrine-disrupting properties of the product should not be included in this opinion. The Chair explained that the opinion should only include such conclusions when any of the co-formulants is identified as an ED or when there are significant indications that a co-formulant is an ED. When this is not the case the outcome of the ED assessment should not be reported in the opinion.

It was discussed whether to postpone the adoption of the opinion. It was indicated that the Commission would not proceed with the decision making process before the PBT status of cyromazine is clarified and – if required - a comparative assessment is performed. Subsequently, several members and the Commission proposed to postpone the adoption. Some members argued that the adoption should be postponed due to the discussion on the metabolite melamine. On the other hand the legal deadline of 180 days for the opinion would not be met if the opinion would not be adopted. In addition, the issue of additional fees when cyromazine would be regarded as a candidate for substitution requiring a comparative assessment was raised. Finally, the Chair proposed to adopt the opinion. The opinion was adopted by consensus with the abstention of five members.

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 29 October 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 5 November 2021 and publish them on the ECHA website.

- **Rapporteur:** to submit the final non-confidential PAR to the SECR by 26 November 2021.

9. Any other business

9.1 Analysis of alternatives

Summary of MSCA survey on analysis of alternatives under the BPR

The SECR presented a summary of the outcome of the questionnaire sent to the members following the BPC-38 on their experience with analysis of alternatives (AoA). The compiled responses document is available in the relevant folder in CIRCABC IG.

The questionnaire addressed several aspects including members' expertise on AoA (technical and economic feasibility, risk reduction of alternatives, identification of alternatives), their possible contribution in an EU network on AoA, feedback on the current process and the use of the AoA borates experience in their biocides-related work. A total of 13 responses were received.

As regard to the expertise on AoA, a lack of internal expertise of MS on technical and economic feasibility, a lack of resources to work on AoAs and a lack of available information on alternatives was reported by several respondents. However, some MSCAs indicated to have built expertise on the technical feasibility aspects some PTs.

The main sources of information on alternatives are the lists of AS and the screening of products in R4BP but eco-labelled products were also mentioned. For non-chemical alternatives: results of the third parties' consultations, literature search, information received from the stakeholders are the main reported information sources.

It was suggested to enhance the reach-out to industry stakeholders and professionals to improve the collection of such information.

No specific biocides AoA network was mentioned except the SCOTTY initiative managed by UBA. Most MS pointed out their limited resources/expertise as a limitation to contribute to such a network but are interested in principle.

The information from BPC opinions or Assessment Reports on alternatives for the comparative assessment of products was used by several MSCAs when available, mainly as a starting point, complemented with additional information (often the national registers for biocidal products).

Several suggestions were made for improving the current process, including having a closer cooperation with REACH AoA/SEA experts and SEAC; improve ECHA databases on approved active substances and authorised products; enhanced involvement of stakeholders such as universities/research institutes, industry/professional users, NGOs; building a list of experts, developing guidance.

Regarding the consultations of interested third parties, the limited resource/expertise and the absence of information on alternatives are the main limiting factors for MSCAs to contribute to the consultations. The development of a template for the public consultation was suggested.

Suggestions for support from ECHA were made, such as the support of the eCA with information on non-chemical alternatives and for processing the information submitted in

the consultations, or the improvement of biocides databases to more easily retrieve pertinent information for AoA (e.g. specific uses, target organisms).

The example of the AoA borates case in MS' biocides-related work is generally considered as much as possible, depending on the particular situation (e.g. AS renewal, first approval, etc.), taking into account the workload and available resources.

The SECR concluded its presentation suggesting building member's expertise through a continued collaboration between MS, stakeholders, ECHA-S (REACH)/SEAC, the development of guidance documents and the use of networking opportunities. The lack of information on alternatives could be partly addressed by an increased reach-out to different types of stakeholders.

Following the presentation, the Netherlands indicated that they would submit their contribution after the meeting. They mentioned that the applicants should get motivated to contribute more to the AoAs and that they would implement further exchanges of information on alternatives between Dutch agencies, also building a list of experts in the field.

The Commission indicated that a collaboration with SEAC could be considered and reminded that it is important to have a right balance of efforts put in AoAs. Amending the BPR to include requirements for applicants to submit information on alternatives for substances meeting the substitution criteria could be considered as well.

Actions:

- **SECR:** to upload the presentation on CIRCABC IG and the updated compiled survey responses document with the input from NL when received.

Progress on guidance development on analysis of alternatives

The SECR presented the summary of a document made available to the members prior to the meeting regarding the suggested approach for the development of the guidance on alternatives and a proposed table of content.

The SECR will develop a guidance and a template for applicants and MSCAs on how to perform the analysis of alternatives. It would provide a set of elements considered important to evaluate the availability of suitable alternatives and a structure for reporting this analysis. However, it would not set clear-cut criteria to decide whether an alternative is suitable and whether there are sufficient alternatives, nor if the derogation criteria under Art 5(2) are successfully met. As a first step, the guidance would aim at describing the necessary content for the analysis of alternatives but not for the other aspects of the derogation criteria under Art 5(2). The guidance could be used by applicants, MSCAs, the BPC and third parties willing to submit information on alternatives.

The guidance would be based on the recent experience on borates, creosote and EtO; the relevant BPC and CA documents; REACH application for authorisation guidance and formats. It is intended to be kept short, describing the key steps and actions to be performed, and providing a structure through a template for documenting the analysis.

A first guidance and template draft are planned to be made available for BPC-42 (Feb-March 2022) with a second draft for BPC-43 (June 2022), aiming at adoption and publication as version 1. Parallel continued discussions with the Commission on the inclusion of the other elements of Art5(2) would take place. In 2023-24 would be a review

of the practice of using the guidance and template and the possible initiation of the update of the documents.

Following the presentation, members discussed the possibility to set clear-cut criteria on the suitability of alternatives, however recognising the difficulty of doing so, since it usually depends on the case. The Commission invited members to share the methodology they use for such assessments at their own national level, as Member States may have such methodology when they take their own position on whether or not an active substance should be approved or a product authorised. The Netherlands indicated that they would share their experience in the field. The Chair clarified that ASO are welcome to contribute to the development of the guidance, noting that Biocides for Europe proposed such support.

The Commission reminded that the substitution principle is key to the BPR and will consider the need for amending and streamlining the process of Art.5(2) analysis. The Commission also indicated that, according to the BPR, the analysis related to Art.5(2) is not excluded from the content of BPC opinions and that further discussions on BPC's role on these issues could take place.

Actions:

- **SECR:** to upload the presentation on the Analysis of alternatives on CIRCABC IG and open a Newsgroup for comments.

10. 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 40th meeting of BPC

5-7 & 12-14 October 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-39	
The revised version of the minutes of BPC-39 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 and to prepare an instruction "manual" on the use of collaboration tool. **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 **22 October 2021.**
6.2 Meeting the timelines: alternatives ways of working. Progress and status.	
The BPC discussed the item and agreed on the proposals of the SECR: no further consideration of the co-rapporteurship and allowing the ad-hoc follow-up process only in dedicated specified situations.	**SECR**: to upload the presentation on the alternative ways of working on 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 BIT for PT 6 and 13	
The BPC <u>adopted by majority</u> the opinion on the approval of the active substance for PT 6. The BPC <u>adopted by consensus</u> the opinion on the approval of the active substance PT 13.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **26 November 2021.** **Member (SE):** to submit the minority position on PT 6 by **21 October 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 **5 November 2021** and publish it on the ECHA website.
7.3 Draft BPC opinion on d-Allethrin for PT 18	
The BPC <u>adopted by majority</u> the opinion on the non-approval of the active substance PT combination.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **26 November 2021.** **Member (CZ):** to submit the minority position by **21 October 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 **5 November 2021** and publish it on the ECHA website.
7.4. Article 75(1)(g) request on "Eligibility of peanut butter active substance for inclusion into Annex I to the BPR"	
The BPC discussed the request and agreed that ECHA will act as the rapporteur.	-
7.5 Revised Assessment Report following the submission of data after active substance approval:	
7.5.1 Permethrin for PT 8 and 18	
The member from IE informed the BPC about the evaluation of the data submitted after the approval. The evaluation was agreed upon.	**Member (IE):** to forward the revised assessment report with the List of Endpoints to the SECR by **5 November 2021.**

Permethrin is considered to be a candidate for substitution.	**SECR:** to revise the status of permethrin in the overview table prepared for the CG.
7.5.2 OIT for PT 18	
The member from FR informed the BPC about the evaluation of the data submitted after the approval. The evaluation was agreed upon. The status of OIT not meeting the P/vP and B/vB criteria following the information provided for the metabolites is confirmed.	**Member (FR):** to forward the revised assessment report with the List of Endpoints to the SECR by **5 November 2021.**
7.6 Article 15(2) request on the review of approval of the active substances iodine, polyvinylpyrrolidone iodine and zineb: rapporteurship for iodine and polyvinylpyrrolidone iodine	
The BPC discussed the request and agreed that SE will act as the rapporteur.	-
Item 8 – Union authorisation	
8.1 Update on Union authorisation	
The BPC took note of the presentation provided by the SECR.	**SECR:** to upload the presentation on the BPC CIRCABC IG.
8.2 Draft BPC opinion an Union authorisation application for a biocidal product 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 **29 October 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 **5 November 2021** and publish them on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **26 November 2021**.
8.3 Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from sodium hypochlorite	
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 **29 October 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 (FR): to submit the minority position by **21 October 2021**. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **5 November 2021** and publish them on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **26 November 2021**.
8.4. Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from calcium hypochlorite	
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 **29 October 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 (DE):** to submit the minority position by **21 October 2021**. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **5 November 2021** and publish them on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **26 November 2021**.
8.5. Draft BPC opinion on an Union authorisation application for a biocidal product containing propan-2-ol	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **29 October 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 **5 November 2021** and publish them on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **26 November 2021**.
8.6. Draft BPC opinion on an Union authorisation application for a biocidal product containing propan-1-ol and propan-2-ol	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **29 October 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 **5 November 2021** and publish them on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **26 November 2021**.
8.7. Draft BPC opinion on an Union authorisation application for a biocidal product containing propan-1-ol and propan-2-ol	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **29 October 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 **5 November 2021** and publish them on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **26 November 2021**.
8.8. Draft BPC opinion on an Union authorisation application for a biocidal product 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 **29 October 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 **5 November 2021** and publish them on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **26 November 2021**.
8.9. Draft BPC opinion on an Union authorisation application for a biocidal product 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 **29 October 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 **5 November 2021** and publish them on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **26 November 2021**.
8.10. Draft BPC opinion on an Union authorisation application for a biocidal product containing cyromazine	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation. Abstain: DE, EL, FI, IT, NL	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **29 October 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 **5 November 2021** and publish them on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **26 November 2021**.
Item 9 – Any other business	
9.1 Progress on guidance development on Analysis of alternatives	
The BPC discussed the item.	SECR: to upload the presentations on the Analysis of alternatives on CIRCABC IG and open a Newsgroup for comments.

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Part III - List of Attendees

Members	SCHMALHOLZ Ellen (SE)
BALDASSARRI Lucilla (IT)	WEINHEIMER Viola (DE)
BORGES Teresa (PT)	**Advisors**
BROVKINA Julija (LV)	AESCHBACHER Michael (CH)
BUEHLER Dominique (CH)	ASK BJÖRNBERG Karolin (SE)
CARBERRY Stephen (IE)	BLOCH Carsten (DE)
CEBASEK Petra (SI)	BOS Carina (NL)
CHEZEAU Aurelie (FR)	BRYS Kristel (BE)
GONZALEZ MARQUEZ Maria Luisa (ES)	CHMELIKOVA Jana (SK)
GREGERSEN Nina Falk (DK)	CONROY Kenneth (IE)
HADJIGEORGIOU Andreas (CY)	COUGNON Thomas (BE)
HAHLBECK Edda (SE)	DE LA USADA Eduardo (ES)
HAKAITE Palmira (LT)	DONZE Gerard (CH)
JÄGER Stefanie (DE)	EHNI Markus (DE)
JARRETY Helene (BE)	FUERTES Pedro (ES)
JOHN Nina (AT)	GEISER Christoph (CH)
KOIVISTO Sanna (FI)	GKILPATHI Dimitra (GR)
LANS Martine (NL)	GRUENIG David (CH)
MERISTE Anu (EE)	HÄMÄLAINEN Anna-Maija (FI)
MIKOLAS Jan (CZ)	HOUAMED Anis (BE)
MIKOLASKOVA Denisa (SK)	HUSZAŁ Sylwester (PL)
RANDALL Marit (NO)	HYVÄRINEN Tuija (FI)
RZODECZKO Helena (PL)	KALKERS Lucas (NL)
SZENTGYORGYI Timea (HU)	KRAFTE Kristine (LV)
VAGIAS Vasileios (EL)	KRUIDHOF Sabine (NL)
VRHOVAC FILIPOVIC Ivana (HR)	LURMAN Glenn (DE)
ZIGRAND Jeff (LU)	MEZULE Linda (LV)
Alternate members	NIEMINEN Timo (FI)
COLLET Romy(FR)	PENTTINEN Sari (FI)
ENSCH Svenja (LU)	PORTELA Cristina (ES)
MALLIA Lothar Paul (MT)	POULIS Joan (NL)
PUERGY Reinhild (AT)	PYTHON Francois (CH)
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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-40

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-40 meeting

Meeting documents		
Agenda Point	**Number**	**Title**
2.	BPC-A-40-2021_rev1	Draft agenda
4.	BPC-M-39-2021	Draft minutes from BPC-39
5.1	-	Administrative issues and report from the other Committees
6.1	BPC-40-2021-01 BPC-40-2021-02 BPC-40-2021-03 BPC-40-2021-04	BPC Work Programmes for active substance approval, Union authorisation, outlook for BPC and ED assessment
6.2	BPC-40-2021-05	Meeting the timelines: alternatives ways of working. Progress and status.
7.1	BPC-40-2021-06	7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval
7.4	BPC-40-2021-20	Article 75(1)(g) request on “Eligibility of peanut butter active substance for inclusion into Annex I to the BPR” Cover note
	BPC-40-2021-21	Mandate
7.5	BPC-40-2021-18A	7.5.1. Permethrin for PT 18
	BPC-40-2021-18B	
	BPC-40-2021-18C	
	BPC-40-2021-18D	
	BPC-40-2021-19A	7.5.2. OIT for PT 8
	BPC-40-2021-19B	
7.6	BPC-40-2021-23	7.6. Article 15(2) request on the review of approval of the active substances iodine, polyvinylpyrrolidone iodine and zineb: rapporteurship for iodine and polyvinylpyrrolidone iodine
8.1	-	Update on Union authorisation
9.1	BPC-40-2021-22A	Progress on guidance development on Analysis of alternatives
	BPC-40-2021-22B	
	BPC-40-2021-22C	

Substance documents				
Agenda Point	**Number**	**Substance-PT**	**eCA**	**Title**
7.2	BPC-40-2021-07A	BIT for PT 6 & 13	ES	Draft BPC opinion
	BPC-40-2021-07B			Assessment report
	BPC-40-2021-07C			Open issues
	n/a			Room document
	n/a			Room document
	n/a			Room document
	n/a			Room document
7.3	BPC-40-2021-08A	d-Allethrin PT 18	DE	Draft BPC opinion
	BPC-40-2021-08B			Assessment report
	BPC-40-2021-08C			Open issues
	BPC-40-2021-08D			Background document
8.2	BPC-40-2021-09A	UA: L(+) Lactic acid	LV	Draft BPC opinion
	BPC-40-2021-09B			SPC
	BPC-40-2021-09C			PAR
	BPC-40-2021-09C1			PAR Conf annex
	BPC-40-2021-09D			Open issues
8.3	BPC-40-2021-10A	UA: active chlorine released from sodium hypochlorite	BE	Draft BPC opinion
	BPC-40-2021-10B			SPC
	BPC-40-2021-10C			PAR
	BPC-40-2021-10C1			PAR Conf annex
	BPC-40-2021-10D			Open issues
8.4	BPC-40-2021-11A	UA: active chlorine released from calcium hypochlorite	FR	Draft BPC opinion
	BPC-40-2021-11B			SPC
	BPC-40-2021-11C			PAR
	BPC-40-2021-11C1			PAR Conf annex
	BPC-40-2021-11D			Open issues
8.5	BPC-40-2021-12A	UA: propan-2-ol	DE	Draft BPC opinion
	BPC-40-2021-12B			SPC
	BPC-40-2021-12C			PAR
	BPC-40-2021-12C1			PAR Conf annex
	BPC-40-2021-12D			Open issues
8.6	BPC-40-2021-13A	UA: propan-1-ol and propan-2-ol	CH	Draft BPC opinion
	BPC-40-2021-13B			SPC

	BPC-40-2021-13C			PAR
	BPC-40-2021-13C1			PAR Conf annex
	BPC-40-2021-13D			Open issues
8.7	BPC-40-2021-14A	UA: propan-1-ol and propan-2-ol	CH	Draft BPC opinion
	BPC-40-2021-14B			SPC
	BPC-40-2021-14C			PAR
	BPC-40-2021-14C1			PAR Conf annex
	BPC-40-2021-14D			Open issues
8.8	BPC-40-2021-15A	UA: hydrogen peroxide	FI	Draft BPC opinion
	BPC-40-2021-15B			SPC
	BPC-40-2021-15C			PAR
	BPC-40-2021-15C1			PAR Conf annex
	BPC-40-2021-15D			Open issues
8.9	BPC-40-2021-16A	UA: hydrogen peroxide	NL	Draft BPC opinion
	BPC-40-2021-16B			SPC
	BPC-40-2021-16C			PAR
	BPC-40-2021-16C1			PAR Conf annex
	BPC-40-2021-16C2			PAR MS Conf annex
	BPC-40-2021-16D			Open issues
	BPC-40-2021-16E			Corrosive study
8.10	BPC-40-2021-17A	UA: cyromazine	CH	Draft BPC opinion
	BPC-40-2021-17B			SPC
	BPC-40-2021-17C			PAR
	BPC-40-2021-17C1			PAR Conf annex MS
	BPC-40-2021-17D			Open issues
	BPC-40-2021-17E			Mail_DE_Melamine
	BPC-40-2021-17F			Attachment_Mail_DE_Melamine
	BPC-40-2021-17G			BPC40_Closed session

24 September 2021
BPC-A-40-2021_rev1

Draft agenda

40th meeting of the Biocidal Products Committee (BPC)

5 – 7 & 12-14 October 2021

Meeting is held virtually via WebEx

Starts on 5 October at 10:30, ends on 14 October at 16:00

The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-40-2021_rev1

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-39

BPC-M-39-2021

For agreement

5. – Administrative issues

5.1. Administrative issues

For information

5.2. Experience in using 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-40-2021-01; BPC-40-2021-02; BPC-40-2021-03; BPC-40-2021-04

For information

6.2. Meeting the timelines: alternatives ways of working. Progress and status.

BPC-40-2021-05
For discussion

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-40-2021-06
For information

7.2. Draft BPC opinion on BIT for PT 6 and 13

Previous discussion: WG-II-2021

BPC-40-2021-07A, B, C
For adoption

7.3. Draft BPC opinion on d-Allethrin for PT 18

Previous discussions: WG-V-2018 & WG-III-2017

BPC-40-2021-08A, B, C, D
For adoption

7.4. Article 75(1)(g) request on "Eligibility of peanut butter active substance for inclusion into Annex I to the BPR"

BPC-40-2021-20; BPC-40-2021-21
For information

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

7.5.1. Permethrin for PT 8 and 18

BPC-40-2021-18A, B, C, D
For agreement

7.5.2. OIT for PT 8

BPC-40-2021-19A, B
For agreement

7.6. Article 15(2) request on the review of approval of the active substances iodine, polyvinylpyrrolidone iodine and zineb: rapporteurship for iodine and polyvinylpyrrolidone iodine

BPC-40-2021-23
For discussion

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

8. – Union authorisation**

8.1 Update on Union authorisation

For information

8.2 Draft BPC opinion on an Union authorisation application for a biocidal product containing L(+) Lactic acid

Previous discussion: WG-II-2021

BPC-40-2021-09A, B, C, D

For adoption

8.3 Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from sodium hypochlorite

Previous discussion: WG-II-2021

BPC-40-2021-10A, B, C, D

For adoption

8.4 Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from calcium hypochlorite

Previous discussion: WG-II-2021

BPC-40-2021-11A, B, C, D

For adoption

8.5 Draft BPC opinion on an Union authorisation application for a biocidal product containing propan-2-ol

Previous discussion: WG-II-2021

BPC-40-2021-12A, B, C, D

For adoption

8.6 Draft BPC opinion on an Union authorisation application for a biocidal product containing propan-1-ol and propan-2-ol

Previous discussion: WG-II-2021

BPC-40-2021-13A, B, C, D

For adoption

8.7 Draft BPC opinion on an Union authorisation application for a biocidal product containing propan-1-ol and propan-2-ol

Previous discussion: WG-II-2021

BPC-40-2021-14A, B, C, D

For adoption

8.8 Draft BPC opinion on an Union authorisation application for a biocidal product containing hydrogen peroxide

Previous discussion: WG-II-2021

** 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).

BPC-40-2021-15A, B, C, D

For adoption

8.9 Draft BPC opinion on an Union authorisation application for a biocidal product containing hydrogen peroxide

Previous discussion: WG-II-2021

BPC-40-2021-16A, B, C, D, E

For adoption

8.10 Draft BPC opinion on an Union authorisation application for a biocidal product containing cyromazine

Previous discussion: WG-II-2021

BPC-40-2021-17A, B, C, D, E, F, G

For adoption

9. – Any other business

9.1 Progress on guidance development on Analysis of alternatives

BPC-40-2021-22A, B, C

For discussion

10. - Action points and conclusions

Provisional time schedule for the

40th meeting of the Biocidal Products Committee (BPC)

Virtual meeting via WebEx

5 October 2021: starts at 10:30; 14 October 2021 ends at 16:00

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.

Tuesday 5 October: (starts at 10:30 EET / 09:30 CET, ends at 17:00 EET / 16:00 CET)

Items 1-5	Opening items and administrative issues
Item 6.1	BPC Work Programmes for active substance approval, Union authorisation, ED assessment and outlook for BPC
Item 6.2	Meeting the timelines: alternatives ways of working. Progress and status.
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 7.6	Article 15(2) request on the review of approval of the active substances iodine, polyvinylpyrrolidone iodine and zineb: rapporteurship for iodine and polyvinylpyrrolidone iodine
Item 7.2	Draft BPC opinion on BIT for PT 6 and 13

Wednesday 6 October: (starts at 10:30 EET / 09:30 CET, ends at 17:00 EET / 16:00 CET)

Item 8.1	Update on Union authorisation
Item 8.3	Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from sodium hypochlorite for PT 2, 3, 4 and 5 (BC-MY047028-07), eCA BE
Item 8.4	Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from calcium hypochlorite for PT 2, 4 and 5 (BC-WK046289-14), eCA FR

Thursday 7 October: (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 containing propan-2-ol for PT 1, 2 and 4 (BC-BL025673-43), eCA DE
Item 8.6	Draft BPC opinion on an Union authorisation application for a biocidal product containing propan-1-ol and propan-2-ol for PT 1 (BC-MU051242-25), eCA CH
Item 8.7	Draft BPC opinion on an Union authorisation application for a biocidal product containing propan-1-ol and propan-2-ol for PT 1, 2 and 4 (BC-AQ050985-22), eCA CH

Tuesday 12 October: (starts at 10:30 EET / 09:30 CET, ends at 17:00 EET / 16:00 CET)

Item 7.3	Draft BPC opinion on d-Allethrin for PT 18
Item 7.4	Article 75(1)(g) request on “Eligibility of peanut butter active substance for inclusion into Annex I to the BPR”
Item 7.5	Revised Assessment Report following the submission of data after active substance approval

7.5.1. Permethrin for PT 8 and 18

Item 8.2 Draft BPC opinion on an Union authorisation application for a biocidal product containing L(+) Lactic acid for PT 2 (BC-XS050968-91), eCA LV

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

Item 8.8 Draft BPC opinion on an Union authorisation application for a biocidal product containing hydrogen peroxide for PT 2, 3 and 4 (BC-WX029254-02), eCA FI

Item 8.9 Draft BPC opinion on an Union authorisation application for a biocidal product containing hydrogen peroxide for PT 2, 3 and 4 (BC-ML029042-45), eCA NL

Item 7.5 (cont'd)

7.5.2. OIT for PT 8

Thursday 14 October: (starts at 10:30 EET/09:30 CET, ends at 16:00 EET/15:00 CET)

Item 8.10 Draft BPC opinion on an Union authorisation application for a biocidal product containing cyromazine for PT 18 (BC-TH035808-24), eCA CH. This agenda item will be preceeded by a closed session on a horizontal aspect related to this application.

Item 9.1 Progress on guidance development on Analysis of alternatives

Item 10 Action points and conclusions

End of meeting

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