20 June 2022

BPC-M-42-2022

Minutes of the 42nd meeting of the Biocidal Products Committee (BPC)

1-3 & 8-9 March

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chair of the Biocidal Products Committee (BPC) welcomed the participants to the 42nd 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.

34 Advisers (of whom 4 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, Article 38 item under agenda point 9 and Article 75(1)(g) item under agenda item 10, 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-42-2022_rev2) 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/Interact 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-41

The revised draft minutes from BPC-41 (BPC-M-40-2021), incorporating the comments received, were agreed.

The Chair mentioned that all actions from the previous BPC-41 meeting were carried out.

Actions:

- **SECR:** to upload the agreed minutes from BPC-41 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 face-to-face meetings when it will be allowed by the ECHA Management. Currently no face-to-face meetings are possible up to 21 March 2022. A policy is being developed on how to return to face-to-face meetings.

5.2 Experience in using Interact Collaboration Tool

Following the experiences in process flow (PF) 42, the use of the Collaboration tool for commenting was amended for PF 43 by the introduction of Excel rather than Word. Later this year ECHA will introduce new user groups, which will allow to involve user groups in a more granular way.

ECHA has received feedback from several Member States, sometimes with opposing requests on further development and opposing views for the future use. ECHA would like to receive feedback on the use of Interact Collaboration in general and the RCOM template in Excel specifically in a more structured way.

ECHA would like to receive the feedback per Member State and proposed that every Member State would compile one report and the BPC member transmits this in one report. For this purpose ECHA will send an email to all BPC members to which they can reply.

Actions for SECR:

- To send an email with instructions on how to provide feedback on the use of Interact Collaboration tool 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 2022 the planned opinions are listed in the “Outlook” document. The total number of adopted opinions will probably be comparable to 2021: the number for UA will increase considerably while for the Review Programme the number will probably be similar.

The Chair asked the evaluating Competent Authorities being rapporteur for active substances or Union authorisations scheduled for discussion at the the second BPC meeting of 2022 (BPC-43) to confirm their planning to the SECR as soon as possible.

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

decisions must still be based under BPD principles, which is becoming more and more problematic.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by **25 March 2022**.

6.2 Update on active substance approval and Union authorisation

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

i) Workload on AS and UA

SECR presented the current workload of AS and UA dossiers in peer-review and the forecast for 2022. It was noted that the cases planned to enter peer-review will increase, more significantly for UA cases.

ii) Update from AS and UA processes

The SECR reminded Member States to update the planning document provided via the Interact Collaboration tool if there are changes in their planning of submissions. In addition, the SECR informed that accordance checks will be shared with Member States at the start of the commenting period, so the ECHA comments can be considered.

A comment was made regarding the timelines for the AS and UA processes, in particular with challenges linked to short steps in the processes, overlap of important steps of different process flows or of important steps of the UA and active substance processes as well as overlap of Working Group and BPC meetings. The latter will challenge the BPC meeting preparation, especially for rapporteurs, if the experts are involved at the Working Group meeting at the same time. ECHA noted the comments, clarified the difficulties in avoiding overlaps and informed that some measures will need to be taken for addressing the higher workload, in particular for the next PF in UA.

In addition, the SECR reminded that updated IUCLID file should be provided at the latest by the BPC opinion closing step.

iii) P statements

The SECR asked two questions in relation to the precautionary (P) statements to be included in the Summary of the Product Characteristics (SPC): 1) who is responsible for deciding the correct working of the combined P statements or P statements which need to be completed with the relevant text included in the SPC (an example is P280: Wear gloves/ protective coverall/eyes/face protection; 2) should the P statement be aligned in Section 3 of the SPC (provided by the CLP) and risk mitigation measures (RMM) statements and/or PPE in Section 4.1. and 5 of the SPC (included those based on the risk assessment)? The members considered that completingthe complex P statements is the responsibility of the applicant. In addition, the members noted that P statements driven by the CLP requirements in Section 3 and statements in Section 4.1. and Section 5 should not be aligned. The discussion in relation to the P statements will be continued in the next CA meeting.

Actions:

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

6.3 Update ECHA on on-going court cases

The SECR gave an update on the on-going court cases related to the BPR where ECHA is involved in.

The Commission further emphasised the importance of the quality of the BPC opinions, in particular on having clear explanations of the conclusions reached in the BPC opinion, and on the identified adverse effects which are critical in the risk assessment performed.

Actions:

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

7. Applications for approval of active substances

7.1 Draft BPC opinion on Methylene dithiocyanate for PT 12

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

The BPC agreed on the Assessment Report for PT 12 and the opinion 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 15 April 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 25 March 2022 and publish it on the ECHA website.

7.2 Draft BPC opinion on (13Z)-Hexadec-13-en-11-yn-1-yl acetate for PT 19

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

The rapporteur France introduced the assessment of the new active substance for (13Z)-Hexadec-13-en-11-yn-1-yl acetate (pheromone) in PT 19 submitted under Article 8(4) of the BPR.

The BPC went through the limited number of comments raised in the open issue table on the Assessment Report and agreed to the proposed ways forward. The BPC agreed on the Assessment Report for PT 19.

The rapporteur explained that a large part of the data set is waived based on the very low exposure to the active substance upon use of the representative biocidal product. This

approach has been accepted following discussions in the Working Group Human Health and Environment. The approach is also suggested in guidance documents that were agreed within the context of other legislations or organisations: plant protection products (PPP) and OECD. This guidance has been taken into account as it is scientifically relevant and as no specific guidance had been developed for the assessment of pheromones under the biocides legislation. The approach was supported, provided that the approval of the active substance is restricted to the use of the representative biocidal product. It was concluded that the rapporteur will add an introductory part in the opinion that further explains the approach taken. The Commission explained that a restriction to a specific biocidal product might lead to further discussions as this is not in line with the approach followed for active substance approval. The rapporteur explained that the reason for restricting the active substance use for professional only without having assessed the use by non-professionals is linked to the mode of application of the active substance. The product is used by professional with the proposed risk management measures (RMM) described.

It was questioned why analytical methods for the stabiliser had not been included into the dossier already and is requested as post approval data instead. The rapporteur explained that the stabiliser was considered part of the active substance following discussions at the Working Group as it was considered that the stabiliser is part of the active substance. The applicant stated that the methods will be available and submitted to the rapporteur before August 2022.

Following a comment from the Commission a paragraph on the expected absence of resistance to the pheromone substance based on the mode of action will be included in the opinion. In addition, an explanation of the human health scenario used for the secondary exposure to the general public will be included in the opinion.

In the proposed restriction of the approval to the use of the representative biocidal product a condition is included to “passive non-retrievable dispenser”. Following a question from one of the members, the rapporteur explained that this is the term used in the PPP guidance document. It means that the dispenser does not need to be retrieved following use, and that the active substance is diffusing from the dispenser by itself (it is not actively “sprayed” out of the dispenser). A footnote will be added to the opinion to describe this type of dispenser.

The Committee adopted the opinion on the active substance by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 15 April 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 25 March 2022 and publish it on the ECHA website.

7.3 Draft BPC opinion on the renewal of Propiconazole for PT 8

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

The rapporteur briefly introduced the case. The submitted dossier for renewal supports the use of propiconazole as wood preservative for use class 2 and 3 of a solvent based

formulation for industrial and professional users. The evaluated application methods cover brushing/rolling, automated spraying and fully automated dipping. It should be noted that there are also authorisations of propiconazole containing products for use classes 3 and 4 wood vacuum-pressure impregnation in the EU. However, the representative product is not used in vacuum-pressure impregnation and this use was not evaluated. The Commission noted that it might be a problem to authorize these uses if the risks are unknown. Resistance in target organisms has not been reported. However, resistance of a human pathogen Aspergillus fumigatus to triazole derivatives used for medical purposes has been reported. The source of the resistance is not yet clear and may also be related to agricultural or animal health use of triazole derivatives. The Commission underlined that this might be an important aspect to, look at during the renewal process. The Commission recently mandated several EU agencies and one Directorate General to analyse the impact of azole fungicides other than as human medicines on the development of thiazole resistant *Aspergillus sp*. The input is expected for July 2024. Though the source is also linked to wood processing industry in the latest studies. Propiconazole meets the exclusion criteria of BPR due to the classification as Repro 1B and the identification as endocrine disruptor of human health. In addition, the substance was identified as endocrine disruptor of non-target organisms in the environment. ED Expert Group was also consulted, and it supported the ED status for humans and the non-target organisms. No unacceptable risks to human health and the environment are identified by the conventional risk assessment when risk mitigation methods are applied. However, so far principles and methodology on conducting risk assessment for endocrine disrupting properties are missing, and thus no conclusion on the level of risks related to endocrine disrupting properties can currently be drawn. The public consultation on alternatives took place in 2021. During the consultation 78 contributions were received. According to the submitted statements there are not sufficient alternatives for all uses of propiconazole. According to the search made by the eCA using the ECHA website in August 2020, around 60% of total authorisations in PT 8 contain propiconazole. Therefore, exclusion of propiconazole would have a major impact on the market and the availability of wood preservatives to the users. In addition, propiconazole has multiple uses within PT 8 which makes the analysis of alternatives challenging.

Renewal Assessment report (RAR):

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

While a detailed risk assessment incorporating the status of the active substance being an endocrine disrupter (for human health and non-target organisms) was provided for peer review, it was not supported in the Working Group Human Health and was therefore removed from the RAR. A member proposed to add more details in the text including the suggested DMEL_ED values and a clarification that the exposure used in the MoE (Margin of Exposure) calculations was the maximum accepted exposure for each scenario. The members disagreed however to include the DMEL as it was not agreed by the Working Group.

A member asked whether there was a mandate to perform a ‘ED risk assessment’, similar to cyanamide and DBNPA discussed at the previous meeting. The Chair explained that this was not the case but that the eCA was asked to perform this assessment also for propiconazole by ECHA during the evaluation phase.

One member expressed reservations whether the substance was shown to induce adverse effect according to the WHO definition. While he agreed that the line of evidence was established showing that the change in AGD (anogenital distance) is substance related effect he does not see how this effect fulfils the definition of adverse effect according to the WHO definition (as mentioned in the ED criteria). emphasizing that the change in morphology also requires that such a change result in an impairment of functional

capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences. It is the second part of the definition that should be specified for AGD. While acknowledging that AGD is a predictor of other adverse effects it is probably not the cause but just a marker. Thus, unless evidence is provided that AGD is the cause of a future functional impairment then under the BPR AGD cannot be considered as an adverse effect. As an adverse effect is an essential condition that must be fulfilled if a substance is to be considered as endocrine disruptor it follows that despite the established ED modality the substance cannot be considered as endocrine disruptor. Similar arguments are applicable to estrous cyclicity which shows abnormality at early developmental stage and then becomes normal at a later stage. The fulfilment of the second part of the above adverse effect definition is not clear. The SECR highlighted that the Working Group Human Health clearly agreed that the substance is an ED, the adversity was demonstrated and that the ED guidance acknowledges that the WHO definition is a general definition and that in the case of EDs expert judgement can be used also on the pattern of effects.

Opinion:

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

The rapporteur clarified that there is no need to submit a new CLH dossier regarding the proposed labelling EUH066.

For the summary tables containing the overall conclusions of the risk assessment for human health and environment it was agreed that the column “Additional PPE/RMM due to ED properties” will be removed, to harmonised the tables and to include for each scenario the conclusion that no conclusion is possible. The latter due to the fact that the ‘ED risk assessment’ was inconclusive. The BPC recommended that clarification is required on how to move forward with active substances meeting the ED criteria, to prevent a reiterating conclusion that the ‘ED risk assessment’ is inconclusive, also in light of resources spent during the evaluation and peer review process. The applicant highlighted that for cyanamide it was concluded that professional use was acceptable and asked if this could also be concluded for propiconazole. The eCA clarified that it is not possible to conclude on the ‘ED risk assessment’, neither for professionals nor for the general public. The Commission asked whether it could be stated more clearly that taking into account the ED properties, it is not demonstrated that the representative product has no unacceptable effect.

Several risk mitigation measures (RMM) were included in the opinion in the human health and environment section. These proposed RMMs were informative, not exhaustive and not reviewed in detail. It was therefore decided to delete these RMMs from the opinion and include the information in the RAR only. This will include the measure to add a top-coat. It was further discussed if it the term RMM can be used as the ‘ED risk assessment’ is inconclusive. It was stated that exposure needs to be minimised as propiconazole meets exclusion criteria so therefore it was suggested to use the term ‘measures’ instead of RMMs. This was accepted by the meeting.

As propiconazole meets the exclusion criteria and is a candidate for substitution, the applicant prepared an impact assessment which was used as the basis for the analysis of alternatives. The eCA prepared an overview of the alternatives per use class and application method. The applicant stated that in its opinion there is no suitable alternative to replace propiconazole. Some – more minor – comments were discussed where it was

also asked to include a more clear conclusion on whether alternatives are available for which uses.

It was proposed by a member to include similar conditions like are now under discussion for the renewal of the approval of creosote related to the placing of the market of treated articles to the current proposal for approval. Several members agreed that such conditions are required, but considered this premature as it is unknown if one of the conditions of Article 5(2) is met which would lead to a possible renewal of the approval. Subsequently, it was proposed to await the discussion in the Standing Committee on Article 5(2). It was therefore agreed to instead add a general statement that according to the BPC provisions for treated articles are needed for propiconazole as it meets the exclusion criteria. One member agreed with this but stated that although the use patterns of creosote and propiconazole are different, the conditions for treated articles for propiconazole probably be similar to the ones which are now under discussion for creosote.

One member raised the question whether for substances meeting the exclusion criteria, all use categories related to treated articles foreseen to fulfil one or more of the derogation criteria in a Member State covered by the biocidal products authorised need to be assessed at renewal stage. Until now, the eCAs assessed only the uses applied for by the applicant which may make it impossible to approve placing on the market of treated articles belonging to use classes not assessesed, even in case Member States identify that one of the derogations of Article 5.2 is applicabe on their territory for treated articles in this use class. This is in addition not covered by the guidance available on renewal of approval published by ECHA. On the other hand covering all existing uses facilitates the decision making process on Article 5.

The BPC agreed on the Renewal Assessment Report (RAR) for PT 8 and the opinion was adopted by majority.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **15 April 2022**.
- **Members (CZ):** to submit the minority opinion by **16 March 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 **25 March 2022** and publish it on the ECHA website.

8. Union authorisation

8.1. Draft BPC opinion on an Union authorisation application for a biocidal product family containing Propan-1-ol

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

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The opinion was adopted by 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 **23 March 2022.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **25 March 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **15 April 2022**.

8.2 Draft BPC opinion on an Union authorisation application for a biocidal product family containing Propan-2-ol

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

There were limited comments on the draft PAR/SPC and BPC opinion. All the identified open points were addressed and closed during the meeting. The BPC members agreed to amend the draft PAR, the draft SPC and the BPC opinion in accordance with the discussion.

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 **23 March 2022.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **25 March 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **15 April 2022**.

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

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

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

The rapporteur briefly introduced a position paper provided by the applicant, addressing the non-authorisation of the products of Meta SPC 3 and 4, which are liquid formulations classified for Serious Eye Damage (H318), which are intended to be used by non-professional users by spraying with a trigger spray.

The applicant requested the BPC to reconsider the non-authorisation and authorise the products with the appropriate risk mitigation measures, or give time to the applicant to amend the product formulation or provide additional data that could be considered by the

authorities. The BPC highlighted that these issues have already been addressed and discussed in the Human Health Working Group. Additionally, several members voiced their support to the rapporteur and agreed with the non-authorisation of Meta SPC 3 and 4 spraying products for non-professional users due to the H318 classification.

The proposed post-authorisation requirement for DSC tests of representative products of all Meta SPCs to confirm the self-reactive properties was supported by the BPC members. Following the discussion, the rapporteur agreed to clarify the reasoning behind this requirement for DSC tests and include an explanation that the test is required for confirmatory purposes only and will not affect the classification.

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 **23 March 2022.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **25 March 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **15 April 2022**.

8.4 Draft BPC opinion on an Union authorisation application for a biocidal product family containing Active chlorine released from sodium hypochlorite

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

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

The applicant was informed about the outcome of the BPC discussion (held earlier in a closed session) where for this UA case, the majority of the members supported the pragmatic evaluation approach, as proposed by the eCA, towards chlorate formation exceeding the reference specification set at active substance approval.

Most of the members disagreed with the eCA's proposal to apply a 50% degradation limit in the storage stability test and sett a shelf-lives for the Meta-SPCs in this family on this basis. The eCA explained that this is done to avoid overdosing and that otherwise it is difficult to perform a complete risk assessment as probably insufficient data is available on the composition of the biocidal product in case the degradation is more than 50%. Several members noted that the chosen degradation limit of 50% is arbitrary and not based on a scientific rationale. As well as it is unclear at what time the counting of degradation should start (as chlorate is generated from the time of manufacturing till the end of the products' shelf-life). They reminded that in such cases, when the 10% limit in the current methodology is exceeded, the shelf-life should be determined following the BPR guidance as laid down in the respective entry of the Technical Agreement for Biocides (TAB APCP) using the efficacy test results for the products covered. The eCA referred to the difficulty to request an efficacy testing for each product in large families, especially

when low concentrations of the *in situ* generated active substance in the product could be expected at the end of the shelf-life. The applicant pointed out that the UA dossier with demonstrated efficacy and safe risk assessment had been prepared in accordance with the information requirements at the time of the submission, while new guidance documents and requirements have been released afterwards that should not be applied retrospectively in this case. The BPC highlighted that further discussion in the relevant Working Groups is needed on the general approach towards rapidly degraded active substances, as the current BPR guidance and the TAB entry do not sufficiently address this. The majority of the members agreed that the current guidance should be followed, so the proposed 50% limit cannot be applied. Therefore, the eCA was requested to verify and amend the proposed shelf-lives for the Meta-SPCs accordingly. It was noted as well that the same issue has been recently discussed but not concluded at the Coordination Group. Here it was concluded to escalate this issue to the Commission for discussion at CA level.

A member pointed out an issue with the efficacy assessment for Meta-SPC B: if the 50% limit is not applied, as the efficacy data of a co-formulant (surfactant) included in the Meta-SPC B products has been based on the 50% consideration. The eCA confirmed and agreed to revise the justification for the set shelf-life following the efficacy considerations instead of the current argumentation.

The BPC members and the applicant supported the suggested splitting of Meta-SPC C in two[1] to allow better adjustment of the active substance ranges (below and above 5% cut-off value) and to ensure the same classification in the whole Meta-SPC. Currently, the Meta-SPC C covers products in an active substance range between 4 and 6%, while labelling with EUH031 is required only for those products with a content of active chlorine higher than 5%.

No support was given to the alternative eCA's suggestions to either specify when EUH031 should be applied in the PAR and SPC or limit the range of the current Meta-SPC to those products with an active substance content up to 5% and ensure the applicant's possibility for change applications for the products with higher active chlorine content.

The eCA agreed to make the relevant shelf-life verifications, the Meta-SPC C splitting and to amend the PAR, SPC and BPC opinion according to the discussion held. However, the eCA noted that this revision would require a re-assessment of the data package in terms of biocidal products' degradation, of the appropriate RMMs (as regards Meta-SPC splitting) and of toxicity and efficacy information. The BPC Chair concluded that the legal deadline of 180 days for peer review and opinion forming of a Union authorisation application cannot be followed in this case, as it is not possible to adopt an opinion without a shelf-life set for all products. Therefore, the adoption of the opinion was postponed for the following BPC meeting[2].

Actions:

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

[1] In line with paragraph (23) of the CA-Nov14-Doc.5.8 – Final: Implementing the new concept of biocidal product families.
[2] After the BPC meeting it was decided to adopt the revised opinion via a written procedure.

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

The Chair welcomed the applicant. The ASOs were allowed to be present during the discussion. The rapporteur briefly introduced the dossier and explained the changes made to the family during the peer review.

The applicant was informed about the outcome of the BPC discussion (held earlier in a closed session) where for this UA case, the majority of the members supported the pragmatic evaluation approach, as proposed by the eCA, towards chlorate formation exceeding the reference specification set at active substance approval.

Initially the family composed of 2 meta SPCs; meta SPC 1 and meta SPC 2. However, due to failure to set a shelf life, because of lacking efficacy data on aged product, the meta SPC 1 cannot be authorised. In addition, the meta SPC 2 was split into two new meta SPCs due to classification of some of the products as corrosive to metals; meta SPC 2A and meta SPC 2B.

All the identified open points were addressed and closed during the meeting. The BPC agreed that the wording in the draft PAR should be amended indicating that efficacy data of aged products was not available at the time of working group meetings as suggested by the eCA.

The applicant requested information on requirements for authorisation of meta SCP 1. It was explained that a major change application needs to be submitted for the eCA to evaluate the submitted efficacy data. In case the efficacy data is sufficiently demonstrating efficacy of the aged product the shelf life can be set and the authorisation can be granted. The change application can be submitted only after the implementing regulation has been adopted.

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

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 **23 March 2022.**
- **Members (BE, CZ and SE):** to submit the minority opinion by **16 March 2022**.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **25 March 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **15 April 2022**.

8.6 Evaluation of post-authorisation data submitted for:

8.6.1 A biocidal product family containing Propan-2-ol for PT 2 and 4

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

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The opinion was adopted by 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 **23 March 2022.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **25 March 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **15 April 2022**.

8.6.2 A biocidal product family containing Propan-2-ol for PT 2 and 4

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

There were no items 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 **23 March 2022.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **25 March 2022** and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by **15 April 2022**.

8.7 Information on two future applications for Union authorisation

An eCA gave an introductory presentation on the structure and the evaluation of the product authorisation reports of two Union authorisation applications with an intended submission for peer review in the next process flow.

9. Article 38 opinion requests

9.1 Request following applications for national authorisation for two biocidal products containing ethyl butylacetylaminopropionate (IR 3535).

The applicant was not present. Stakeholders were allowed to be present during the discussion. The rapporteur briefly introduced the dossier and the questions of the mandate.

All items in the open issues table were addressed and conclusions reached were recorded in the open issues table. The comments received did not lead to the necessity to amend the opinion.

The opinion was adopted by consensus.

Actions:

- **SECR:** to forward the adopted opinion to COM by **25 March 2022** and publish it on the ECHA website.

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

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

The Chair welcomed the applicant. The stakeholders were allowed to be present during the discussion. The rapporteur briefly introduced the case. A first version of the draft opinion was presented for discussion. The rapporteur went through a selected number of issues from the open issues table to be specifically addressed.

The applicant also made a presentation, summarising the issues they had raised in the open issue table. A member indicated that a report from the Canary Island local authorities on the use of biocidal products against termites was available and will submit it to the rapporteur.

Discussions took place regarding the inclusion in the analysis of potential alternatives pertaining to PT 8. This was recognised not to be explicitly requested in the Article 75(1)(g) mandate and including them would lead to significant additional work, jeopardising the deadline to finalise the opinion. It was concluded that if BPC members have specific information of potential alternatives from PT 8 relevant for this case they can submit it to the rapporteur.

The comparison of efficacy of hexaflumuron and the alternative diflubenzuron towards the same target organisms was discussed. It was agreed that this issue would be further assessed and developed in the next version of the opinion. Similarly, the risk assessment of the alternative diflubenzuron was discussed, including the issue of its metabolites. It was agreed that this issue would be described in the the next version of the opinion, however probably without performing a detailed comparative assessment. It was also propose to add hexaflumuron in the tables summarising the chemical alternatives in order to enable a comparison with other substances.

Actions:

- **SECR:** to initiate an additional commenting period until **8 April 2022**.

- **Rapporteur:** to revise the draft opinion and submit it to the SECR by **2 May 2022.**

11. Any other business

11.1 Draft guidance Analysis of alternatives to biocidal active substances for applicants and MSCAs

The SECR introduced the background for the draft guidance and highlighted specific elements regarding its content and the related process.

Two members recognised the added value of the guidance but raised their concerns regarding its implementation by the MSCAs at active substance level due to lack of resources, arguing that it would not be implementable in the short term. One of these members also addressed the lack of data requirements (especially for candidates for substitution) and raised the concern that, in the extent proposed, such an analysis of alternatives (AoA) could not be implemented in the active substance evaluation process and would need a separate procedure.

Regarding the risk assessment of alternatives another member highlighted that at AS level only the hazard can be looked at, leaving the risk assessment to product authorisation level.

Two other members recognised the comprehensive nature of the draft guidance but underlined the requirement from the BPR to address the alternatives for substances being a candidate for substitution. One of the member suggested to have separate guidance documents for applicants and MSCAs.

At the end of the discussion, the Chair summarised the discussion, indicating the probable need for adopting a tiered approach adapted to the case.

Actions:

- **SECR:** to initiate a commenting period until **8 April 2022**.
- **SECR:** to discuss internally on the next steps.

12. 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 42nd meeting of BPC

1-3 & 8-9 March 2022

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom / by when)**
Item 2 - Agreement of the agenda	
The final draft agenda was agreed without changes.	**SECR:** to upload the agreed final agenda to the BPC CIRCABC IG/Interact as part of the draft meeting minutes after the meeting.
Item 4 - Agreement of the minutes and review of actions from BPC-41	
The revised version of the minutes of BPC-41 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 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 **25 March 2022.**
6.2 Update on active substance approval and Union authorisation	
The BPC took note of the presentation provided by the SECR and agreed on some of the questions raised in it.	**SECR:** to upload the presentation on Interact/BPC CIRCABC IG.
6.3 Update ECHA on on-going court cases	
The BPC took note of the presentation provided by the ECHA.	**SECR:** to upload the presentation on Interact/ BPC CIRCABC IG.

Item 7 - Applications for approval of active substances	
7.1 Draft BPC opinion on Methylene dithiocyanate for PT 12	
The BPC adopted by consensus the opinion on the approval of the active substance for PT 12.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **15 April 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 **25 March 2022** and publish it on the ECHA website.
7.2 Draft BPC opinion on (13Z)-Hexadec-13-en-11-yn-1-yl acetate for PT 19	
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 **15 April 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 **25 March 2022** and publish it on the ECHA website.
7.3 Draft BPC opinion on the renewal of Propiconazole for PT 8	
The BPC adopted by majority the opinion on the approval of the active substance for PT 8.	**Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **15 April 2022.** **Members (CZ):** to submit the minority position by **16 March 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 **25 March 2022** and publish it on the ECHA website.
Item 8 – Union authorisation	
8.1 Draft BPC opinion on an Union authorisation application for a biocidal product family containing Propan-1-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 **23 March 2022.**

	SECR: to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **25 March 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **15 April 2022**.
8.3 Draft BPC opinion on an Union authorisation application for a biocidal product family 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 **23 March 2022.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **25 March 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **15 April 2022**.
8.4 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 **23 March 2022.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **25 March 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **15 April 2022**.
8.5 Draft BPC opinion on an Union authorisation application for a biocidal product family containing active chlorine released from sodium hypochlorite	
The BPC postponed the adoption of the opinion.	
8.6 Draft BPC opinion on an Union authorisation application for a biocidal product family 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 **23 March 2022.**

	Members (BE, CZ, SE): to submit the minority position by **16 March 2022.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **25 March 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **15 April 2022**.
8.6 Evaluation of post-authorisation data submitted for:	
8.6.1 A biocidal product family containing Propan-2-ol for PT 2 and 4	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) in accordance with the discussions in the BPC and submit to the SECR by **23 March 2022.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion and PAR to COM by **25 March 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **15 April 2022**.
8.6.2 A biocidal product family containing Propan-2-ol for PT 2 and 4	
The BPC adopted by consensus the opinion on the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) in accordance with the discussions in the BPC and submit to the SECR by **23 March 2022.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion and PAR to COM by **25 March 2022** and publish the opinion on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **15 April 2022**.
8.7 Information on two future applications for Union authorisation	
The BPC took note of the presentation provided by the FR CA.	**SECR:** to upload the presentation on the Interact/BPC CIRCABC IG.
Item 9 – Article 38 opinion requests	
9.1 Request following applications for national authorisation for two biocidal products containing ethyl butylacetylaminopropionate (IR 3535).	

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 **25 March 2022** and publish it on the ECHA website.
Item 10 – Article 75(1)(g) opinion requests	
10.1 Draft BPC opinion on the evaluation of the availability and suitability of alternatives to hexaflumuron for PT 18	
The BPC discussed the draft opinion on this request.	**Rapporteur:** to revise the draft opinion for discussion and adoption at BPC-43. **SECR:** to upload the presentation by EL & by the applicant on Interact/BPC CIRCABC IG and open a Newsgroup/Collaboration for commenting.
Item 11 – Any other business	
11.1 Draft guidance Analysis of alternatives to biocidal active substances for applicants and MSCAs.	
The BPC took note of the presentation provided by the SECR and discussed the draft guidance.	**SECR:** to upload the presentation on Interact/BPC CIRCABC IG and to revise the draft guidance for BPC-43 and open a Newsgroup/Collaboration for commenting.

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Part III - List of Attendees

Members	Advisors
BALDASSARRI Lucilla (IT)	AMPATZI Argyro (GR)
BORGES Teresa (PT)	ASK BJÖRNBERG Karolin (SE)
BROVKINA Julija (LV)	ASLING Bengt (SE)
BUEHLER Dominique (CH)	AUBIN Aurelie (FR)
CARBERRY Stephen (IE)	BELINGAARD Valerie (FR)
CEBASEK Petra (SI)	BUJARD Thomas (FR)
CHEZEAU Aurelie (FR)	BURMISTROVA Anastasia (BE)
DRAGOIU Simona (RO)	CHABOT Esther (FR)
GONZALEZ MARQUEZ Maria Luisa (ES)	CHMELIKOVA Jana (SK)
GREGERSEN Nina Falk (DK)	EHNI Markus (DE)
HADJIGEORGIOU Andreas (CY)	GIATROPOULOS Athanasios (GR)
HAHLBECK Edda (SE)	GKILPATHI Dimitra (GR)
HAKAITE Palmira (LT)	GOUR Annabelle (FR)
JAGER Stefanie (DE)	HÄMÄLAINEN Anna-Maija (FI)
JARRETY Helene (BE)	IAKOVIDOU Mary (SE)
JOHN Nina (AT)	KAUKONIEMI Sanna (FI)
KOIVISTO Sanna (FI)	KUNDERT Antje (NL)
MIKOLAS Jan (CZ)	MALMGREN Birgitta (SE)
MIKOLASKOVA Denisa (SK)	NIKOLOPOULOU Dimitra (GR)
RANDALL Marit (NO)	PARR Mervyn (IE)
RZODECZKO Helena (PL)	PORUBIAKOVA Jadza (SK)
SZENTGYORGYI Timea (HU)	RIFFAUT Lea (FR)
VAGIAS Vasileios (EL)	RUIZ LOPEZ Elena Fuensanta (ES)
VRHOVAC FILIPOVIC Ivana (HR)	RYDEN Andreas (SE)
ZIGRAND Jeff (LU)	SAFHOLM Moa (SE)
Alternate members	SCHMALHOLZ Ellen (SE)
COLLET Romy (FR)	SIX Therese (FR)
COUGNON Thomas (BE)	TALHOUET Anne-Claire (Fr)
KALKERS Lucas	VÄLIMÄKI Elina (FI)
MALLIA Lothar Paul (MT)	VUORENSOLA Katariina (FI)
PYTHON Fracois (CH)	WEINHEIMER Viola (DE
SULG Helen (EE)	

Commission Observers	CARLON Claudio
CHATELIN Ludovic (DG SANTE)	DE WOLF Watze
DELVAUX Vincent (DG SANTE)	ESTEVAN MARTINEZ Carmen
TSIAMIS Konstantinos (DG SANTE)	HÄMÄLÄINEN Eva
Accredited Stakeholder Observers	HONKA Anni
AROZAMENA RAMOS Eduardo	KREBS Bernhard
BARBU Luminita	LAITINEN Jaana
COGGINS Christopher	MACKEVICA Aiga
RUELENS Paul	MARCON Eva
VAN BERLO Boris	MATTHES Jochen
WEISS Aharon	MOTTET Denis
Applicants	MUELLER Gesine
Colgate-Palmolive Sp. Z.o.o.	RAULIO Mari
Contec Cleanroom (UK) Limited	SAEZ RIBAS Monica
Corteva Agriscience	SCHIMMELPFENNIG Heike
Ecolab Deutschland GmbH	STASKO Jolanta
Lanxess Deutschland GmbH	SZANTO Emese
M2i Biocontrol	SZYMANKIEWICZ Katarzyna
Pal International Limited	VALKOVICOVA Eva
Reckitt Benckiser Production (Poland) Sp z o.o.	VAN DE PLASSCHE Erik
Solvay Solutions UK Limited	VAN DER LINDEN Sander
Velltek Associates Inc. Europe	VAN GALEN Joost
ECHA Staff	VASILEVA Katya
BUCHANAN Camilla	

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-42

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-42 meeting

Agenda Point	Number	Title		
2.	BPC-A-42-2022	Draft agenda		
4.	BPC-M-41-2021	Draft minutes from BPC-41		
5.1	–	Administrative issues and report from the other Committees		
5.2	-	Experience in using the Interact Collaboration Tool		
6.1	BPC-42-2022-01 BPC-42-2022-02 BPC-42-2022-03 BPC-42-2022-04 Presentation	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		
6.3	Presentation	Update ECHA on on-going court cases		
8.7	Presentation	Information on two future applications for Union authorisation		
11.	BPC-42-2022-17 BPC-42-2022-18 Prsentation	Draft guidance Analysis of alternatives		
12.		Any other business		
Agenda Point	**Number**	**Substance-PT**	**eCA**	**Title**
7.1	BPC-42-2022-05A	Methylene dithiocyanate (MBT) for PT 12	FR	Draft BPC opinion
	BPC-42-2022-05B			Assessment report
	BPC-42-2022-05C			Open issues
7.2	BPC-42-2022-06A	(13Z)-Hexadec-13-en-11-yn-1-yl acetate for PT 19 (pheromone)	FR	Draft BPC opinion
	BPC-42-2022-06B			Assessment report
	BPC-42-2022-06C			Open issues
	BPC-42-2022-06D			Ref specs
	BPC-42-2022-06E			Ref specs_conf annex
7.3	BPC-42-2022-07A	Propiconazole for PT 8 - renewal	FI	Draft BPC opinion
	BPC-42-2022-07B			Renewal Assessment report
	BPC-42-2022-07C			Open issues

	BPC-42-2022-07D			RAR_APPENDIX_VI-1
	BPC-42-2022-07E			RAR_APPENDIX_VI-2
	BPC-42-2022-07F			RAR_APPENDIX_VI-3
	BPC-42-2022-07G			RAR_APPENDIX_VI-4
	BPC-42-2022-07H			RAR_Technical_Equivalence
	BPC-42-2022-07I			Minimisation EE
	BPC-42-2022-07J			Minimisation HE
	BPC-42-2022-07K			Ref_spec_updated
8.1	BPC-42-2022-08A	UA: Propan-1-ol	SE	Draft BPC opinion
	BPC-42-2022-08B			SPC
	BPC-42-2022-08C			PAR
	BPC-42-2022-08C1			PAR Conf annex
	BPC-42-2022-08D			Open issues
8.2	BPC-42-2022-09A	UA: Propan-2-ol	NL	Draft BPC opinion
	BPC-42-2022-09B			SPC
	BPC-42-2022-09C			PAR
	BPC-42-2022-09C1			PAR Conf annex
	BPC-42-2022-09D			Open issues
8.3	BPC-42-2022-10A	UA: L-(+)-lactic acid	FR	Draft BPC opinion
	BPC-42-2022-10B			SPC
	BPC-42-2022-10C			PAR
	BPC-42-2022-10C1			PAR Conf annex
	BPC-42-2022-10D			Open issues
8.4	BPC-42-2022-11A	UA: active chlorine released from sodium hypochlorite (BC-NB046342-57)	FR	Draft BPC opinion
	BPC-42-2022-11B			SPC
	BPC-42-2022-11C			PAR
	BPC-42-2022-11C1			PAR Conf annex
	BPC-42-2022-11D			Open issues
	BPC-42-2022-11 &12 E			Ref. specs & degradation
	Presentation			8.4 & 8.5 closed session presentation
8.5	BPC-42-2022-12A	UA: active chlorine released from sodium hypochlorite (BC-EF047438-44)	FR	Draft BPC opinion
	BPC-42-2022-12B			SPC
	BPC-42-2022-12C			PAR
	BPC-42-2022-12C1			PAR Conf annex
	BPC-42-2022-12D			Open issues
8.6	BPC-42-2022-13A		DE	Draft BPC opinion

	BPC-42-2022-13B	8.6.1 Propan-2-ol for PT 2 and 4 (BC-DY025578-07)		PAR
	BPC-42-2022-13C			Open issues
	BPC-42-2022-14A	8.6.2 Propan-2-ol for PT 2 and 4 (BC-LA025582-58)		Draft BPC opinion
	BPC-42-2022-14B			PAR
	BPC-42-2022-14C			Open issues
9.1	BPC-42-2022-15A	Art. 38 National authorisation for two biocidal products containing ethyl butylacetylaminopropionate (IR 3535)	ECHA	Draft BPC opinion
	BPC-42-2022-15B			Open issues
10.1	BPC-42-2022-16A	Art. 75(1)(g) Evaluation of the availability and suitability of alternatives to hexaflumuron for PT18	EL	Draft BPC opinion
	BPC-42-2022-16B			Open issues
	BPC-42-2022-16C_room_doc1			Room document

18 February 2022
BPC-A-42-2022_rev2

Draft agenda

42nd meeting of the Biocidal Products Committee (BPC)

1-3 & 8-9 March 2022

Meeting is held virtually via WebEx

Starts on 1 March at 10:30, ends on 9 March at 17:00

The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-42-2022

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-41

BPC-M-41-2021

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-42-2022-01; BPC-42-2022-02; BPC-42-2022-03; BPC-42-2022-04

For information

6.2. Update on active substance approval and Union authorisation

For information

6.3. Update ECHA on on-going court cases

For information

7. – Applications for approval of active substances‡

7.1. Draft BPC opinion on Methylene dithiocyanate for PT 12

Previous discussion: WG-IV-2021

BPC-42-2022-05A, B, C

For adoption

7.2. Draft BPC opinion on (13Z)-Hexadec-13-en-11-yn-1-yl acetate for PT 19

Previous discussion: WG-IV-2021

BPC-42-2022-06A, B, C, D, E

For adoption

7.3. Draft BPC opinion on the renewal of Propiconazole for PT 8

Previous discussion: WG-IV-2021

BPC-42-2022-07A, B, C, D, E, F, G, H, J, K

For adoption

8. – Union authorisation**

8.1. Draft BPC opinion on an Union authorisation application for a biocidal product family containing Propan-1-ol

Previous discussion: WG-IV-2021

BPC-42-2022-08A, B, C, D

For adoption

8.2. Draft BPC opinion on an Union authorisation application for a biocidal product family containing Propan-2-ol

Previous discussion: WG-IV-2021

BPC-42-2022-09A, B, C, D

For adoption

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

Previous discussion: WG-IV-2021

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

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

BPC-42-2022-10A, B, C, D

For adoption

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

Previous discussion: WG-IV-2021

BPC-42-2022-11A, B, C, D, E

For adoption

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

Previous discussion: WG-IV-2021

BPC-42-2022-12A, B, C, D, E

For adoption

8.6 Evaluation of post-authorisation data submitted for:

8.6.1 A biocidal product family containing Propan-2-ol for PT 2 and 4

BPC-42-2022-13A, B, C

For adoption

8.6.2 A biocidal product family containing Propan-2-ol for PT 2 and 4

BPC-42-2022-14A, B, C

For adoption

8.7 Information on two future applications for Union authorisation

For information

9. – Article 38 opinion requests

9.1 Request following applications for national authorisation for two biocidal products containing ethyl butylacetylaminopropionate (IR 3535).

BPC-42-2022-15A, B

For adoption

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

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

BPC-42-2022-16A, B

For discussion

11. - Any other business

11.1 Draft guidance Analysis of alternatives to biocidal active substances for applicants and MSCAs.

BPC-42-2022-17, BPC-42-2022-18

For discussion

12.– Action points and conclusions

Provisional time schedule for the

42nd meeting of the Biocidal Products Committee (BPC)

Virtual meeting via WebEx

1 March 2022: starts at 10:30; 9 March 2022 ends at 17:00

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

Tuesday 1 March: (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 6.3	Update ECHA on on-going court cases
Item 8.1	Draft BPC opinion on an Union authorisation application for a biocidal product family containing Propan-1-ol, PT 01 (BC-RS050191-24)
Item 8.2	Draft BPC opinion on an Union authorisation application for a biocidal product family containing Propan-2-ol, PT 02, 04 (BC-HN024859-20)

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

Item 8.3	Draft BPC opinion on an Union authorisation application for a biocidal product family containing L-(+)-lactic acid, PT 02 (BC-HK051319-37)
Item 8.6	Revised assessment following the submission of post-authorisation data for:
	8.6.1 A biocidal product family containing Propan-2-ol for PT 2 and 4
	8.6.2 A biocidal product family containing Propan-2-ol for PT 2 and 4
Item 9.1	Request following applications for national authorisation for two biocidal products containing ethyl butylacetylaminopropionate (IR 3535).

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

Item 8.4	Draft BPC opinion on an Union authorisation application for a biocidal product family containing active chlorine released from sodium hypochlorite, PT 02, 04 (BC-NB046342-57)
Item 8.5	Draft BPC opinion on an Union authorisation application for a biocidal product family containing active chlorine released from sodium hypochlorite, PT 02 (BC-EF047438-44)

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

Item 7.1	Draft BPC opinion on Methylene dithiocyanate for PT 12
Item 7.2	Draft BPC opinion on (13Z)-Hexadec-13-en-11-yn-1-yl acetate for PT 19
Item 8.7	Information on two future applications for Union authorisation

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

Item 7.3	Draft BPC opinion on the renewal of Propiconazole for PT 8
Item 10.1	Draft BPC opinion on the evaluation of the availability and suitability of alternatives to hexaflumuron for PT 18
Item 11.1	Draft guidance Analysis of alternatives to biocidal active substances for applicants and MSCAs
Item 12	Action points and conclusions

End of meeting

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