10 November 2021

BPC-M-39-2021

Minutes of the 39th meeting of the Biocidal Products Committee (BPC)

15-18 June 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 39th BPC meeting which took place as a virtual meeting via Webex.

The Chair informed the meeting on the upcoming changes in the composition of the BPC Secretariat, Anni Honka replacing Terhi.

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

12 Advisers and 8 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-39-2021_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 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-38

The revised draft minutes from BPC-38 (BPC-M-38-2021), incorporating the comments received, were agreed.

The Chair mentioned that all actions from the previous BPC-38 meeting were carried out:

- templates for the BPC opinions for active substance first approval and renewal and for the BPC opinion for Union authorisation were revised and published on CIRCA;

- the instruction manuals for preparing the BPC opinions for active substance approval (first approval and renewal) and Union authorisation were revised and published on CIRCA;
- ECHA initated guidance development on the analysis of alternatives for applicants and Member States. At BPC-40 the SECR will report in more detail on the progress made, which will include an analysis of the results of the questionnaire.

Actions:

- **SECR:** to upload the agreed minutes from BPC-38 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-40 and 41 will be meetings of more than one week and that both meetings will be virtual.

The SECR gave a short presentations on Interact tool. One member asked what will happen with the 'old documents' stored now in CIRCA. ECHA responded that here no decision has been taken yet but that these documents will at least be available for another year. Commission asked if the meeting documents can be downloaded in 'one go'. ECHA responded this will need to be investigated. Another members asked if members will receive notifications where it was clairified by ECHA this is not possible currently but it is envisaged to be implemented in the future. In addition it was clarified by ECHA that though collaborations will not 'disappear' once the dead-line is passed, it will not possible to make a contribution anymore. Last, ECHA clarified that changes made will not be visible in the online version of a document, but that previous versions of the document concerned can be viewed and downloaded where track-changes are visible.

Actions:

SECR: to publish the presentations on the BPC S-CIRCABC IG.

6. Work Programme for BPC

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

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

The Chair stated that:

- For 2021 the planned opinions are listed in the "Outlook" document. For AS and UA these numbers are given once the dossiers are submitted, which just occured for process flow 41 for UA so these are the "maximum" numbers for 2021. The total number of adopted opinions will be comparable to 2020: 43 versus 38. The number for UA increased from 10 to 15 and AS – Review Programme from 15 to 17.

- For 2022 an increase is still expected however for both AS and UA, although for process flow 41 the increase for UA did not occur (19 expected versus 2 submitted).
- Four opinions following an Article 75(1)(g) request are scheduled for 2021 (which includes an additional request from the Commission received on the Annex I inclusion of peanut butter) and one Article 38. More Article 38 requests are expected but probably for adoption in 2022.
- Reference to the status of ED assessment was made for information purposes. The Chair metioned there are no changes compared to the overview presented for BPC-38 and that there is no decision from the CA meeting yet on whether an ED assessment is required if the active substance is already meeting the exclusion criteria.

The Chair asked the eCAs being rapporteur for active substances or Union authorisations scheduled for discussion at the October 2021 BPC meeting (BPC-40), to confirm this planning to the SECR by 16 August 2021.

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. It was stated that 44 backlog reports still need to be finalised where 8 Member States (MS) are involved as evaluating Competent Authority (eCA). Commission also informed that the Article 65 report on the implemention of the BPR has been sent to the Council and the EU Parliament, and includes among other a state of play on the delays.

Actions:

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

6.2 Meeting the timelines: alternative ways of working

The Chair presented the document “Increase of BPC workload: the short-term perspective” which was followed by a discussion on each of the three short-term actions proposed:

- The meeting welcomed the increase of the preparation time before the meeting with another week for BPC-40 and 41;
- Some comments were given on the revised more structured templates for the open issue tables. These comments will be taken into account by the SECR for BPC-40. Several members expressed concerns on the use of the Interact Collaboration Tool starting for Union authorisations already with Process Flow 41 without any earlier pre-announcement (the tool will be used in the peer review phase up to the Working Group discussions) indicating that more detailed comments will be provided to ECHA after the meeting. Some members explained that the tool does not fit with their internal organisation. In addition, the lack of receiving notification was considered an issue.

- Several members expressed reservations on the idea of the SECR to distribute the commenting of dossiers for BPC-40 and 41 among the members. Several members preferred to have flexibility to be able to comment on a certain dossier depending on resource and expertise availability and the importance of the dossier for their MS. The Chair still made an inventory of those members volunteering to comment on a certain dossier for BPC-40.

Thereafter, the SECR gave a presentation on the alternative ways of working. This presentation covered proposals on adjusting the way of working with the challenges of meeting the peer-review timelines with the current limitations on resources while the workload on AS and UA is increasing. Two main actions taken up from the active substance approval workshop in 2019 and presented to WG-I-2021 were discussed with the intention of getting additional feedback from the BPC before considering any implementation:

- The concept of co-rapporteurship for the peer-review and the feedback from the WGs was presented. Only few MSs were in favour of the approach, with the main issues 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 proposal of removing adhoc follow-ups (AHFUs) was also brought for discussion. The BPC members supported to use AHFUs only in defined situations (e.g. where an additional assessment or additional information is needed) and considered that defining cases will help to restrict its use to situations where it is really necessary.

Based on initial feedback received and additional feedback expected by MSs via Newsgroups, ECHA will consider to revise further the draft proposal.

Actions:

SECR: to publish the documents on the BPC S-CIRCABC IG and open a Newsgroup on "Meeting the timelines: alternative ways of working".

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-38.

Actions:

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

7.2. Draft BPC opinion on L(+) lactic acid for PT 6

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

The rapporteur briefly introduced the case and indicated that L(+) lactic acid is already approved for PT 1, 2, 3 and 4.

There were limited comments on the assessment report and the draft BPC opinion. A proposal from one of the members on the inclusion of a condition on the placing on the market of treated articles was accepted with some modifications. All other comments were agreed by the BPC and the conclusions recorded in the open issue table.

The Assessment Report was ageed 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 30 July 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 6 July 2021 and publish it on the ECHA website.

7.3. Article 15(2) request on the review of approval of the active substances iodine, polyvinylpyrrolidone iodine and zineb

The Chair informed the meeting that ECHA has received this request from the Commission for an Article 15(2) opinion. For these requests a member should act as rapporteur, the foreseen practice would be that the evaluating competent authority acts as the rapporteur for 'their' active substance. The Chair indicated that Sweden was the evaluating competent authority for iodine and PVP iodine but declined being rapporteur in relation to this mandate. The Chair informed that Ireland will act as the rapporteur for zineb whereas there is no rapporteur yet for iodine and PVP-iodine.

7.4. Article 75(1)(g) request on "Evaluation of the availability and suitability of alternatives to hexaflumuron for PT18"

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 Greece will act as the rapporteur. Some information was provided by the rapporteur and the SECR on the initiation of a consultation to provide information on alternatives for this active substance. One member referred to a REACH restriction proposal for PFAS where hexaflumuron is indicated. The SECR will further look into this.

7.5. Article 75(1)(g) request on "Questions relating to a guidance on rodent traps developed by the German Environment Agency"

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.

7.6. Article 75(1)(g) request on "Questions relating to an EU comparative assessment of anticoagulant rodenticides"

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. One member indicated that cholecalciferol is – compared to the comparative assessment which took place under the first renewal – now available as another chemical alternative. The Chair confirmed that this active substance will be considered in the analysis noting cholecalciferol meets the exclusion criteria as well. Another member asked if a new active substance, which is currently in the peer review process, will be considered in the comparative assessment. The Chair stated that this will be problematic as this active substance is not yet approved but the suggestion will be taken into consideration.

8. Union authorisation

8.1 Update on Union authorisation

An update on Union authorisation was given by the SECR.

Actions:

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

8.2 Reporting ED properties in the UA BPC opinion

The Chair introduced the document which is a revision of a document agreed at an earlier BPC. The revision is due to the distinction made - following an agreement at the March 2021 Biocides CA meeting – between co-formulants having indications or having significant indications of endocrine disrupting properties. The document was agreed by the meeting.

Actions:

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

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

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

Product Assessment Report (PAR)

The first issue to be discussed concerned the use for disinfection of swimming pools and hot tubs where it was proposed by the rapporteur that this use should not be authorised. The reason is that the efficacy for viruses and bacteria was not demonstrated as the required test was submitted too late in the peer review process (a letter of access was submitted after the Working Group discussions) to be taken into account. The following elements concerning this issue were discussed:

- Several members raised their concerns on the proposal to not authorise the biocidal product for this use due to the importance of active chlorine released from chlorine for their territory. Not authorising this use would lead to complications for their territory as illustrated in the meeting (see below). These members proposed to

take the test submitted into account despite the fact that this would mean that the 180 days timeline for adopting the opinion cannot be met.

- It was clarified by the rapporteur that an efficacy test for viruses (a so-called Phase 2 Step 1 test) was lacking in the submission by the applicant. This was raised by the rapporteur as early as the pre-submission phase. In the evaluation submitted for peer review by the rapporteur it was proposed to authorise this use, following additional information provided during the evaluation phase. However, following commenting it was proposed by several members during the so-called trilaterals, that efficacy was not demonstrated and subsequently the use cannot be authorised. The rapporteur decided to accept this majority view of the Efficacy Working Group (EFF WG) members and concluded accordingly. Although concerns may be raised over this process (as conclusions changed significantly here and the applicant had no possibility to provide comments), it was clarified by the Chair that according to the SECR the procedures of the Union authorisation process (as laid down in the working procedures published on the ECHA web-site) were followed correctly.
- The applicant clarified that already early on, it was recognised that the existing test protocols for the Phase 2, Step 1 test had to be adapted with respect to the use in swimming pools and hot tubs. In addition, the applicant stated that it was recognised that a field test with viruses is not possible. The fact that first a suitable protocol had to be developed and agreed by the EFF WG, and that the applicant decided to get access to the relevant data instead of carrying out the test, led to delays and the situation that the test was not available before the EFF WG.
- It was clarified by one of the members that the test was received for an application for which the corresponding Member State acts as eCA. The applicant for this product requested and obtained access to the relevant data of this test. The member stated that the evaluation by their efficacy expert resulted in the conclusion that efficacy for viruses is demonstrated. The Chair stated – to which the members agreed – that peer review would be required of this conclusion of the eCA via a discussion in the EFF WG. The Chair clarified that an additional argument for the need for peer review is that the test has now also been submitted for other applications. The Chair clarified that the peer review of this test would lead to an exceedance of the three year period set by the BPR by which a decision on an application for authorisation needs to be taken. The rapporteur clarified that this was an important reason for them – i.e. to respect this legal dead-line of the BPR - to submit their evaluation for peer review.
- One member stated that they considered that efficacy is sufficiently demonstrated based on the literature study included in the dossier. In addition, this member proposed to authorise the use in swimming pools and hot tubs without a virucidal claim.
- Some members referred to the importance of this product for their territory as it is a frequently used disinfectant for public pools. In addition, it is complex to change to another disinfectant due to the nature of chlorine. Other members stated that the BPC should not consider the market impact as a valid argument.
- Overall, the majority of the members expressed the view to not take the efficacy test with viruses still into account. Here some members stated that it can be accepted, but only as an exceptional case while others raised concerns that accepting the test so late in the process would create an unwanted precedent.

- The possibilities of a major change application were discussed in case the authorisation for the use in swimming pools and hot tubs will not be granted. The Commission stated that it needs to be investigated if Article 89(4) applies and stated it will be challenging to grant a major change within one year of the decision by the Standing Committee on this application. The applicant informed the BPC concerning the complications with respect to a major change application, where one was that i swimming pools are not allowed have stocks of chlorine for a period of 6 months because of the risks associated with it. In relation to the situation to the non-availability of this product during the major change procedure for the disinfection of public pools, the Commission indicated that the application of Article 55(1) would be challenging as granting a derogation requires that a measure is necessary because of a danger to public health.
- The possibilities of a derogation under Article 44(5) of the BPR were discussed.

The proposed risk mitigation measures (RMMs) for the use “disinfection of waste water after the waste-water treatment plant” was discussed. Some members stated that this is not a common use with their territory, but could accept the RMMs proposed. One member could not accept the RMMs and considered to submit a derogation under Article 44(5). It was discussed if the retention time in the buffer should be specified in the PAR and SPC. It was clarified by the rapporteur that the time of 19 hours indicated in the PAR is a worst-case situation. It was discussed if it would not be sufficient to add something like “adequate retention time”. It was also discussed if the RMMs should not be combined with the requirement to regularly assess the water quality. It was concluded that the rapporteur would reflect on these proposals when revising the PAR and SPC. It was confirmed by the rapporteur that there is a need for the regular assessment of the water quality although the RMMs itself are considered sufficient to mitigate the risks. The reason is that these measurements are needed to determine how much reducing agent has to be added.

The use disinfection of animal drinking water was discussed. Here it was concluded to add the following in the PAR related to possible residues of chlorate: “However, during product assessment no analytical method to measure chlorate levels in water was available (an analytical method has been recently approved, CAR December 2020) and the WG-I-2021 agreed that no dietary risk assessment should be conducted in the absence of product-specific measurement data. In order to reduce the consumer risk of exposure to chlorate residues in food commodities of animal origin the following RMM is to be added to the SPC: "For food commodities, ensure that the concentration of chlorate present in food does not exceed the MRL values set in Regulation 2020/749". Here the Commission raised concerns over the absence of a MRL derived under Regulation (EU) 470/2009 as the use concerns animal husbandry. The Commission referred to Article 19(1)(e) and Article 19(8) in the BPR. The agreed CA document on the interim approach on MRLs specifies which type of MRL is required for which use. The European Medicines Agency has developed a specific procedure for the setting of MRLs for biocides used in animal husbandry. r. The members considered the RMM introduced however sufficient.

Summary of Product Characteristics (SPC)

Following some discussion it was concluded that the temperatures and pH values specified for the different uses in the SPC will be removed, where the temperatures may be retained in the PAR as these are related to the test conditions. The reason for removing the temperatures, is the varying temperatures of actual raw water in the different MS. It was

clarified by the rapporteur that the demonstration of efficacy at a certain test temperature covers a broader range of temperatures.

Concerns were raised by a member over the inclusion of trained professionals as well as professional as user categories. First, the type of training required (or certification) is not specified. Second, this would in principle mean that a member state requiring only professionals or only trained professionals will need to ask for a derogation according to Article 44(5). It was confirmed by the applicant that certification is required in some member states but it was not possible to specify this further. It was decided to add "professionals and/or trained professionals if required by national legislation" to Section 6 (Other information) of the SPC. This was considered the best option to avoid derogations.

Several members stated that they are considering to submit a derogation under Article 44(5) for various reasons indicated in their comments.

BPC opinion

It was decided to include the CAS number for chlorine in the opinion following a request from several members.

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 BPC 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 28 June 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 6 July 2021 and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by 30 July 2021.
- **Members minority (DE and NL):** to submit the minority position by 2 July 2021.

8.4. 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.

There were limited comments on the draft PAR, SPC and BPC opinion. The description of the use was clarified (disinfection can either take place during the main wash or in the first rinse, depending on whether there is a pre-wash step or not) including the statement that the use of the detergent and disinfectant should not be combined.

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 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 28 June 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 6 July 2021 and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by 30 July 2021.

8.5 Draft BPC opinion on an Union authorisation application for a biocidal product containing permethrin

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

A limited number of comments concerning the draft PAR were discussed. Mainly the BPC members followed the proposals made by the SECR in the open issues table. Regarding classification of permethrin, it was agreed to follow the classification given in the CLP inventory, except for the chronic M-factor which will be kept in line with the Assessment Report agreed at the approval stage of permethrin. It was indicated by the rapporteur that this will not affect the classification of the product.

The content of permethrin in the final product will be kept in the PAR and SPC. This is not in line with the current CA document on handling carriers, nevertheless, it was pointed out that this document does not cover bednets and needs to be updated. COM clarified that CA documents are no legal documents and that the CA document is currently revised by ECHA and a MS. This gap in the CA document affected also further issues like the content of permethrin in the long-term storage study, surface tension, self-heating substances and mixtures, and corrosivity to metals, for which deviations were accepted.

With reference to the self-heating substances and mixtures, it was agreed that the test to be performed on the impregnation liquid can be waived and the current waiver in the PAR will be corrected by the rapporteur in cooperation with the SECR. The same approach was taken for the corrosivity to metals test, which can be waived and there is no post-authorisation data requirement anymore.

The main discussion focused on the dermal absorption value used for permethrin. The Chair highlighted that the issue of whether the evaluation carried out at approval stage should be reconsidered, was raised already several times at the Human Health Working Group where the debate is ongoing now at the Coordination Group. One member indicated their disagreement with the approach followed (i.e. the evaluation carried out at approval stage was not amended) but clarified their agreement with the outcome of the evaluation for this application. It was clarified that for this specific case, if the value is amended due to use of the most recent EFSA guidance this will not impact the outcome of the evaluation made. Nevertheless, it was pointed out that the dermal absorption value is product specific and for consistency reason with other permethrin related cases should be derived for each product individually based on information available in the new guidance. Finally, the BPC accepted the value used in the evaluation.

The inconsistency concerning ethanol as a SoC between the human health and environment sections will be corrected: ethanol will not be considered as a SoC, as it is not present in the final product.

With reference to the draft SPC, there was no discussion, the BPC followed the proposals made in the open issues table. The Chair informed that the warning sentence for bees agreed at the CA meeting is added in Section 5.3. This sentence needs to be added to all future permethrin containing biocidal product cases as an interim measure.

With reference to the BPC opinion in the efficacy section the phrase 'where there is a threat of vector-borne diseases spread by the claimed mosquito species' will be removed to be in line with the opinion of the Efficacy Working Group.

A discussion took place concerning the status of permethrin with respect to it being considered as a candidate for substitution. It was clarified by the Chair that the vP and T status were confirmed by the Environment Working Group, but not yet confirmed by the BPC. Some members stated that as permethrin is a candidate for substitution a comparative assessment had to be performed, which should be reflected in the opinion. The Chair referred to an on-going discussion at the CA meeting on considering new information on the status of an active substance or co-formulant during product authorisation. The Commission clarified that a discussion took place in the CA meeting on how and when to take into account new information available during the product authorisation stages.

It was agreed to not request a comparative assessment and include in the opinion that permethrin is not a candidate for substitution. The Commission made a reservation that this has to be considered further which may have implications for the authorisation of this product.

No further discussion took place in relation to the other open points; the BPC followed the proposals made in the open issues table. The BPC 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 28 June 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 6 July 2021 and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by 30 July 2021.
- **Member minotirty (FI):** to submit the minority position by 2 July 2021.

9. Article 38 opinion requests

9.1 Request following an application for national authorisation for a biocidal product containing permethrin

The Chair welcomed the applicant. The stakeholders were allowed to be present during the discussion. ECHA briefly introduced the Article 38 request and the draft opinion related to a national authorisation for a biocidal product containing permethrin.

The BPC members agreed with the proposals made by the SECR in the open issues table. A proposal to include a condition related to the use of binding agents for wool carpets was rejected by the members as it was confirmed by some of the members and the applicant that binding agents are used for fabric intending for clothing but not for carpets.

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 28 June 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 6 July 2021 and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by 30 July 2021.

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

10.1 Request following an application for Union authorisation for a biocidal product family containing CMIT/MIT

The Chair welcomed the applicant. The stakeholders were allowed to be present during the discussion. The SECR and the rapporteur introduced the draft opinion and the underlying report related.

The applicant raised some concerns over the evaluation performed related to the possibility to estimate the dioxin formation from vehicles. These concerns were however not shared by the rapporteur and the members. There were no other comments on the draft opinion. The opinion was adopted by consensus.

The Commission informed that further consultations with the Member States are probably required to get information on the essentiality – including possible alternatives - of this biocidal product family for this use.

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 28 June 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 6 July 2021 and publish them on the ECHA website.
- **Rapporteur:** to submit the final non-confidential PAR to the SECR by 30 July 2021.
- **SECR**: to upload the presentations from the SECR and the rapporteur to S-CIRCABC.

11. Any other business

11.1 Presentation AISE on “Request Developing household hygiene to meet 21st century needs: A collaborative industry/academia report on cleaning and disinfection in homes & Analysis of European consumers’ hygiene beliefs and behaviour in 2020”

The Chair invited AISE to present this report. Some discussion took place after the AISE presentation.

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 39th meeting of BPC

15-18 June 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-38	
The revised version of the minutes of BPC-38 was agreed.	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website.
Item 5 – Administrative issues	
-	**SECR**: to upload the presentation on the use of Interact on CIRCABC IG
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 June 2021.**
Item 6.2 - Meeting the timelines: alternative ways of working	
The BPC discussed the item.	**SECR**: to upload the presentation on the alternative ways of working on CIRCABC IG and open a Newsgroup for comments.

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 L(+) lactic acid for PT 6	
The BPC adopted by consensus the opinion on the 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 **30 July 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 **6 July 2021** and publish it on the ECHA website.
7.3 Article 15(2) request on the review of approval of the active substances iodine, polyvinylpyrrolidone iodine and zineb	
The BPC discussed the request and agreed that the member from IE will act as the rapporteur for zineb.	**SECR**: to inform the BPC on the rapporteur for iodine / PVP-iodine
7.4. Article 75(1)(g) request on "Evaluation of the availability and suitability of alternatives to hexaflumuron for PT18"	
The BPC discussed the request and agreed that the member from EL will act as the rapporteur.	-
7.5 Article 75(1)(g) request on "Questions relating to a guidance on rodent traps developed by the German Environment Agency"	
The BPC discussed the request and agreed that ECHA will act as the rapporteur.	-
7.6 Article 75(1)(g) request on "Questions relating to an EU comparative assessment of anticoagulant rodenticides"	
The BPC discussed the request and agreed that ECHA 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 Reporting ED properties in the UA BPC opinion	

The BPC discussed and agreed on the document.	**SECR**: to publish the document on the BPC CIRCABC IG and the ECHA website.
8.3 Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from chlorine	
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 **2 July 2021.** **Members (DE and NL):** to submit the minority position by **2 July 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 **6 July 2021** and publish them on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **30 July 2021**.
8.4. Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from sodium hypochlorite	
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 **2 July 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 **6 July 2021** and publish them on the ECHA website. **Rapporteur:** to submit the final non-confidential PAR to the SECR by **30 July 2021**.
8.5. Draft BPC opinion on an Union authorisation application for a biocidal product containing permethrin	
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 **28 June 2021.** **Member (FI):** to submit the minority position by **2 July 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 **6 July 2021** and publish them on the ECHA website.

	Rapporteur: to submit the final non-confidential PAR to the SECR by **30 July 2021**.
Item 9 – Article 38 opinion requests	
9.1 Request following an application for national authorisation for a biocidal product containing permethrin	
The BPC adopted by consensus the opinion.	**SECR:** to forward the adopted opinion to COM by **6 July 2021** and publish it on the ECHA website.
Item 10 – Article 75(1)(g) opinion requests	
10.1. Request following an application for Union authorisation for a biocidal product family containing CMIT/MIT	
The BPC adopted by consensus the opinion.	**Rapporteur:** to revise the underlying report in accordance with the discussions in the BPC and submit to the SECR by **28 June 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 **6 July 2021** and publish it on the ECHA website.
Item 11 –Any other business	
11.1. Presentation AISE on "Request Developing household hygiene to meet 21st century needs: A collaborative industry/academia report on cleaning and disinfection in homes & Analysis of European consumers' hygiene beliefs and behaviour in 2020"	
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Part III - List of Attendees

Members
BALDASSARRI Lucilla (IT)
BORGES Teresa (PT)
BROVKINA Julija (LV)
CARBERRY Stephen (IE)
CEBASEK Petra (SI)
CHEZEAU Aurelie (FR)
DRAGOIU Simona (RO)
GONZALEZ MARQUEZ Maria Luisa (ES)
GREGERSEN Nina Falk (DK)
HADJIGEORGIOU Andreas (CY)
HAHLBECK Edda (SE)
HAKAITE Palmira (LT)
JAGER Stefanie (DE)
JARRETY Helene (BE)
JOHN Nina (AT)
KOIVISTO Sanna (FI)
LANS Martine (NL)
MERISTE Anu (EE)
MIKOLAS Jan (CZ)
MIKOLASKOVA Denisa (SK)
RANDALL Marit (NO)
RZODECKO Helena (PL)
SZENTGYORGYI Timea (HU)
VAGIAS Vasileios (EL)
VRHOVAC FILIPOVIC Ivana (HR)
Alternate members
ENSCH Svenja (LU)
MALLIA Lothar Paul (MT)
PYTHON François (CH)
Advisers
CHMELIKOVA Jana (SK)
COLLET Romy (FR)
DE RIVAS Ana (ES)
DUBOISSET Arnaud (FR)
EHNI Markus (DE)
HÄMÄLÄINEN Anna-Maija (FI)
HUSZAŁ Sylwester (PL)
KRAFTE Kristine (LV)
LEROY Céline (BE)
RIFFAUT Léa
VILLUMSEN Rasmus (DK)
WEINHEIMER Viola (DE)
European Commission
CAINZOS Garcia Marta (DG SANTE)
CHATELIN Ludovic (DG SANTE)
DELVAUX Vincent (DG SANTE)
GKINIS Georgios (DG SANTE)
NAGTZAAM Martinus (DG SANTE)
Accredited Stakeholder Observers
BARBU Luminita
COGGINS Christopher
DREVE Simina
HANON Nathalie
MIHAI Camelia
SEJOURNE Valerie
VAN BERLO Boris
WEISS Aharon
Applicants
ARCHE Consortia
Christiansen S.A.R.L.
Corbion (Purac Biochem BV)
Nutrition & Biosciences Netherlands B.V.
Procter & Gamble Services Company NV

Thor GmbH	RUGGERI Laura
ECHA Staff	SAEZ RIBAS Monica
CARLON Claudio	SCHAKIR Yasmin
ESTEVAN MARINEZ Carmen	SCHIMMELPFENNIG Heike
GUTIERREZ ALONSO Simon	STASKO Jolanta
HONKA ANNI	SZANTO Emese
KREBS Bernhard	SZYMANKIEWICZ Katarzyna
KURONEN Terhi	VAN DE PLASSCHE Erik
PAPADAKI Paschalina	VAN GALEN Joost
RAULIO Mari	

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-39

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-39 meeting

Meeting documents		
Agenda Point	**Number**	**Title**
2	BPC-A-39-2021_rev2	Draft agenda
4	BPC-M-38-2021	Draft minutes from BPC-38
5.1	-	Administrative issues and report from the other Committees
6.1	BPC-39-2021-01 BPC-39-2021-02 BPC-39-2021-03 BPC-39-2021-04	BPC Work Programmes for active substance approval, Union authorisation, outlook for BPC and ED assessment
6.2	BPC-39-2021-05	Meeting the timelines: alternative ways of working
7.1	BPC-39-2021-06	7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval
7.3	BPC-39-2021-15A	Article 15(2) request on the review of approval of the active substances iodine, polyvinylpyrrolidone iodine and zineb
	BPC-39-2021-15B	
7.4	BPC-39-2021-16A	Article 75(1)(g) request on “Evaluation of the availability and suitability of alternatives to hexaflumuron for PT18”
	BPC-39-2021-16B	
7.5	BPC-39-2021-17A	Article 75(1)(g) request on “Questions relating to a guidance on rodent traps developed by the German Environment Agency”
	BPC-39-2021-17B	
7.6	BPC-39-2021-18A	Article 75(1)(g) request on “Questions relating to an EU comparative assessment of anticoagulant rodenticides”
	BPC-39-2021-18B	
8.1	-	Update on Union authorisation
8.2	BPC-39-2021-08	Reporting ED properties in the UA BPC opinion
11.1	BPC-39-2021-12A	Presentation AISE on “Request Developing household hygiene to meet 21st century needs: A collaborative industry/academia report on cleaning and disinfection in homes & Analysis of European consumers’ hygiene beliefs and behaviour in 2020”
	BPC-39-2021-12B	

Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**

7.2	BPC-39-2021-07A	Lactic acid PT 6	Draft BPC opinion
	BPC-39-2021-07B		Assessment report
	BPC-39-2021-07C		Open issues
8.3	BPC-39-2021-09A	UA: product containing active chlorine released from chlorine	Draft BPC opinion
	BPC-39-2021-09B		SPC
	BPC-39-2021-09C		PAR
	BPC-39-2021-09C1		PAR Conf annex
	BPC-39-2021-09D		Open issues
	BPC-39-2021-09E		Applicant position paper
8.4	BPC-39-2021-10A	UA: product containing active chlorine released from sodium hypochlorite	Draft BPC opinion
	BPC-39-2021-10B		SPC
	BPC-39-2021-10C		PAR
	BPC-39-2021-10C1		PAR Conf annex
	BPC-39-2021-10D		Open issues
8.5	BPC-39-2021-11A	UA: product containing permethrin	Draft BPC opinion
	BPC-39-2021-11B		SPC
	BPC-39-2021-11C		PAR
	BPC-39-2021-11C1		PAR Conf annex
	BPC-39-2021-11D		Open issues
9.1	BPC-39-2021-13A	Art.38 Request following an application for national authorisation for a biocidal product containing permethrin	Draft BPC opinion
	BPC-39-2021-13A		Draft BPC opinion sanitised APPL version
	BPC-39-2021-13B		RCOM table TOX WG e-consultation
	BPC-39-2021-13C		Appendix 1: Dermal absorption study US EPA
	BPC-39-2021-13D		Appendix 2: BfR Opinion permethrin
	BPC-39-2021-13E		Open issues
10.1	BPC-39-2021-14A	Art.75(1)(g) Request following an application for Union authorisation for a biocidal product family containing CMIT/MIT	Draft BPC opinion
	BPC-39-2021-14B		Response to the EU Commission mandate requesting ECHA opinions under Article 75(1)(g) of the BPR
	BPC-39-2021-14C		Open issues

1 June 2021
BPC-A-39-2021_rev2

Draft agenda

39th meeting of the Biocidal Products Committee (BPC)

15 – 18 June 2021

Meeting is held virtually via WebEx

Starts on 15 June at 10:30, ends on 18 June at 14:00

The time is indicated in Helsinki time.

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-39-2021

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-38

BPC-M-38-2021

For agreement

5. – Administrative issues

5.1. Administrative issues

For information

6. – Work programme for BPC

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

BPC-39-2021-01; BPC-39-2021-02; BPC-39-2021-03; BPC-39-2021-04

For information

6.2. Meeting the timelines: alternative ways of working

BPC-39-2021-05

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-39-2021-06

For information

7.2. Draft BPC opinion on L(+) lactic acid for PT 6

Previous discussion: WG-I-2021

BPC-39-2021-07A, B, C

For adoption

7.3. Article 15(2) request on the review of approval of the active substances iodine, polyvinylpyrrolidone iodine and zineb

BPC-39-2021-15

For information

7.4. Article 75(1)(g) request on "Evaluation of the availability and suitability of alternatives to hexaflumuron for PT18"

BPC-39-2021-16

For information

7.5. Article 75(1)(g) request on "Questions relating to a guidance on rodent traps developed by the German Environment Agency"

BPC-39-2021-17

For information

7.6. Article 75(1)(g) request on "Questions relating to an EU comparative assessment of anticoagulant rodenticides"

BPC-39-2021-18

For information

8. – Union authorisation**

8.1. Update on Union authorisation

For information

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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).

8.2. Reporting ED properties in the UA BPC opinion

BPC-39-2021-08

For agreement

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

Previous discussion: WG-I-2021

BPC-39-2021-09A, B, C, D

For adoption

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

Previous discussion: WG-I-2021

BPC-39-2021-10A, B, C, D

For adoption

8.5. Draft BPC opinion on an Union authorisation application for a biocidal product containing permethrin

Previous discussion: WG-I-2021

BPC-39-2021-11A, B, C, D

For adoption

9. – Article 38 opinion requests

9.1. Request following an application for national authorisation for a biocidal product containing permethrin

BPC-39-2021-12

For adoption

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

10.1. Request following an application for Union authorisation for a biocidal product family containing CMIT/MIT

BPC-39-2021-13

For adoption

11.- Any other business

11.1. Presentation AISE on "Request Developing household hygiene to meet 21st century needs: A collaborative industry/academia report on cleaning and disinfection in homes & Analysis of European consumers' hygiene beliefs and behaviour in 2020"

BPC-39-2021-14

For information

12. - Action points and conclusions

Provisional time schedule for the

39th meeting of the Biocidal Products Committee (BPC)

Virtual meeting via WebEx

15 June 2021: starts at 10:30; 18 June 2021 ends at 14:00

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 15 June: (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: alternative ways of working
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 7.2	Draft BPC opinion on L(+) lactic acid for PT 6
Item 7.3	Article 15(2) request on the review of approval of the active substances iodine, polyvinylpyrrolidone iodine and zineb
Item 7.4	Article 75(1)(g) request on "Evaluation of the availability and suitability of alternatives to hexaflumuron for PT18"
Item 7.5	Article 75(1)(g) request on "Questions relating to a guidance on rodent traps developed by the German Environment Agency"
Item 7.6	Article 75(1)(g) request on "Questions relating to an EU comparative assessment of anticoagulant rodenticides"

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

Item 8.1	Update on Union authorisation
Item 8.2	Reporting ED properties in the UA BPC opinion
Item 8.3	Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from chlorine
Item 8.4	Draft BPC opinion on an Union authorisation application for a biocidal product containing active chlorine released from sodium hypochlorite

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

Item 10.1	Request following an application for Union authorisation for a biocidal product family containing CMIT/MIT
Item 9.1	Request following an application for national authorisation for a biocidal product containing permethrin

Friday 18 June: (starts at 10:30 EET / 09:30 CET, ends at 14:00 EET / 13:00 CET)

Item 8.5	Draft BPC opinion on an Union authorisation application for a biocidal product containing permethrin
Item 11.1	Presentation AISE on “Request Developing household hygiene to meet 21st century needs: A collaborative industry/academia report on cleaning and disinfection in homes & Analysis of European consumers’ hygiene beliefs and behaviour in 2020”
Item 12	Action points and conclusions

End of meeting

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