6 October 2020

BPC-M-35-2020

Minutes of the 35th meeting of the Biocidal Products Committee (BPC)

16-18 June 2020

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chair of the Biocidal Products Committee (BPC) welcomed the participants to the 35th BPC meeting which took place for the first time as a fully virtual meeting via Secure Webex.

Regarding the BPC membership, the Chair stated that there is a new appointed alternate BPC member from Denmark: Stine Jensen.

The Chair then informed the BPC members of the participation of 24 members, including two alternate members and one member whose official nomination is pending. In addition, Poland was represented by an invited expert.

28 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.

The Chair indicated that the next three BPC meetings will be virtual: BPC-36, BPC-37 and BPC-38. For the period thereafter ECHA is aiming to organise all of its meetings for 75% virtually. An internal advisory group has been established to investigate how this target can be achieved.

2. Agreement of the agenda

The Chair introduced the final draft agenda (BPC-A-35-2020_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 would be 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-34

The revised draft minutes from BPC-34 (BPC-M-34-2020), incorporating the comments received, were agreed.

The Chair noted that all actions from BPC-34 have been carried out.

The Chair further informed the meeting on the following:

- The revised document prepared by the SECR on RMM for the BPRS (revised version of the document providing the context of the listed RMMs for a next consultation round) will be circulated again to the BPRS for their June meeting. This item will subsequently come back at the appropriate BPC meeting.
- The CG document "Practical approach for the assessment of ED properties of a biocidal product by rMS/eCA", relevant for the evaluation of Union authorisation applications.
- Post approval data: before the BPC meeting in December 2019 the Chair informed the BPC that further consultation was needed between ECHA and the Commission on how to consider post-approval data, either requested via section 2.5 of the BPC opinion or submitted within an application for product authorisation. The Chair stated that this consultation is unfortunately still on-going where it is foreseen to have discussions in the near future at the CG. However, following internal discussions it has been decided by ECHA to continue with the evaluation of post-approval data requested in section 2.5 of the BPC opinion. The reason for this decision is that further delaying these discussions would hamper the progress of product authorisation applications. The SECR will take action to enable the discussion of some on-going evaluations at the BPC in October, for example on three active chlorine releasers.

Actions:

- **SECR:** to upload the agreed minutes from BPC-34 to the BPC CIRCABC IG and to the ECHA website after the meeting.

5. Administrative issues

5.1 Housekeeping issues

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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 active substance approval 20 opinions are to be adopted this year of which 17 are for the Review Programme, compared to 3 last year. Also 10 opinions will be adopted for the Review Programme being returned opinions via Article 75(1)(g) for ED assessment.

- For Union authorisation the number of opinions to be adopted this year is 11, which is one more compared to 2019.
- Furthermore the outlook for 2020 contains 1 Article 75(1)(g) (a request related to active chlorine generated via electrolysis). In addition another request is under preparation for DBNPA in PT 4. Two other requests may still arrive.
- Maybe some Article 38 opinions will still be requested this year by the Commission: ECHA is waiting for 4 confirmed requests since the end of 2019, where a maximum of 7 more may arrive.
- Reference was made to the status of ED assessment for information purposes. The Chair mentioned that ECHA is preparing an overview for all active substances. This overview will however be included in the ECHA reporting on the Active Plan on Active Substance Approval to the CA meeting. The Chair mentioned 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 2020 BPC meeting (BPC-35), to confirm this planning to the SECR by 24 August 2020.

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, in particular to deliver the draft assessment reports and to not postpone discussions on their substances from BPC meeting to meeting. Progress must also be made on backlog reports submitted before 1 September 2013. Reference was also made to the agreement of ECHA Action Plan on Active Substance Approval which must be implemented.
As regards to Union authorisation, the Commission also expressed concerns on delays.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by **26 June 2020**.

7. Applications for approval of active substances

7.1. Draft BPC opinion on carbon dioxide generated from propane, butane or a mixture of both by combustion for PT 19

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

The eCA briefly introduced the case. The discussion focussed then on the comments on the assessment report and the draft BPC opinion, as included in the open issues table and on the eCA's responses to them.

The Committee thoroughly discussed a proposed provision for product authorisation regarding the conditions that prospective applicants should follow to measure the concentration of the active substance generated *in situ* in different devices.

Following the eCA's clarification that in this case the assessment was focused on the exhaust of the *in situ* generated carbon dioxide as released from the device in

consideration of the natural background concentration of CO_2, the members agreed to include the provision in the BPC opinion but with a different wording. This wording implies that not in all cases measurements will be required but that it can be demonstrated by other means that the conditions of the provision are met.

The BPC concluded that the active substance is eligible for Annex I inclusion. COM explained that they will either include the active substance in the Union list or in Annex I.

Consequently, BPC adopted by consensus the BPC opinion and the AR for this active substance.

In conclusion, the Chair noted that the BPC opinion and the AR will be revised according to the conclusions made by the BPC and reflected in the open issue table.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 30 July 2020.
- **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 3 July 2020 and publish it on the ECHA website.

7.2. Draft BPC opinion on C(M)IT for PT 6

The Chair welcomed the applicant. The ASOs were allowed to be present during the discussion. The discussion focussed on the items included in the open issues table regarding the comments on the assessment report and the draft BPC opinion.

The rapporteur pointed out that no biocidal products containing C(M)IT are currently on the EU market and the active substance was considered as a new active substance by the applicant. However, C(M)IT has been listed on Annex I of EU Regulation 2032/2003 and should therefore be considered as an existing active substance. The Chair commented that items 4 and 5 included in the open issues table relate to this status of the active substance. The Chair noted that C(M)IT is currently considered to be an existing active substance as indicated by the rapporteur. Therefore, the BPC opinion, CAR and AR would need to be amended to reflect this. The Chairman recommended that a decision on this topic is outside the remit of the BPC. The Commission confirmed that C(M)IT should be regarded as an existing active substance as it is listed on Annex I of EU Regulation 2032/2003 setting an exhaustive list of existing active substances (ie. present on the EU market before 14 May 2000), based on the identification process. The applicant noted that only recently they were informed that C(M)IT is now regarded as an existing active substance. The applicant referred to the consequences of this decision and expressed the opinion that C(M)IT ended up on the list of existing active substances by error, stating that it was common in the United States to describe the reaction mass by identifying the components separately. The Chair concluded that the open issues table will mention that C(M)IT is an existing active substance as indicated in the opinion. However, there will be further consultation on this between the applicant and Commission.

A discussion took place about item 13 (and 14) regarding the conclusion of risk characterisation for environment for the scenario 6.2 “Paints and coating” where the use

is considered non-acceptable in case of direct rainwater discharge and a mixed sewer system. The applicant expressed some concerns because the scenario may limit product authorisations to indoor use only whereas the outdoor use is a very important use. The applicant argued that according to the guidance this scenario should not be used for decision-making process. However, a decision was obviously made. The rapporteur commented that the conclusion has no direct impact on the approval of the active substance and is in line with the agreement of the Environment Working Group. However, in order to have an acceptable risk for the environment, further refinement would be necessary at product authorisation and additional data needed with the aim to demonstrate acceptable risks for this scenario. Considering this scenario and the provision in the guidance that it should not be used for decision-making, the Chair commented that there are more cases where unacceptable risks were identified. This may need to revisiting the issue within the CG and/or WG.

One member pointed out that the terminology for the primary and secondary exposure scenario should be in line with previous BPC agreements. The rapporteur will check and update the assessment accordingly.

A discussion took place about item 31 regarding the fact that it was not possible to conclude on the ED assessment. The rapporteur explained that the criterion for human health are not fulfilled however the dataset in the dossier is not sufficient to conclude for the environment on non-target organisms. More information is required which may take about 2 years and half to be obtained. Considering the conclusion on human health and in order not to delay the approval of C(M)IT, the rapporteur proposed to proceed with the adoption of the opinion and request confirmatory data in section 2.5. Several members acknowledged that the proposal is not in line with the current procedure and may create a precedent for other dossiers where a lack of data prevents a conclusion on the ED properties. It was confirmed that this situation occurs and will probably occur more for non-target organisms. Some members shared the view that it is a specific situation where C(M)IT is unlikely to have ED properties and would accept the proposal. One member questioned whether it would be confirmatory data to support the absence of ED properties or additional data to fulfil a data gap that might lead to a different conclusion on ED properties. Another member pointed out the fact that many members are struggling with the ED assessment of the active substances and in case of the acceptance of such proposal, it might be needed to revisit the available guidance. The Commission had sympathy with the attempt to make progress on the dossier but highlighted that ED data are core data, and there are now clear criteria and guidance for the identification and assessment of ED properties of an active substance: therefore, conclusions on ED are required for both human health and environment (section A and B of the annex of Regulation (EU) 2017/2100) as requested in the BPR. The Commission advised the BPC members not to adopt the opinion because there is actually missing information to reach a valid conclusion. In addition, the Commission pointed out that in case the BPC would conclude on the opinion in its present form, it may be returned or a non-approval decision may be recommended due to the lack of data to conclude on the ED properties. In a vote the majority of the BPC members rejected the proposal from the rapporteur. Consequently, the rapporteur will continue with the evaluation in order to finalise the assessment of ED properties. SECR will prepare a note for the next CA meeting to discuss this type of situation where insufficient data are often available for non-target organisms more horizontally as it occurs more often and may have a significant impact on the progress of active substance dossiers like C(M)IT, and for the Review Programme in general.

The remaining issues indicated in the open issues table were agreed.

Actions:

- **Rapporteur:** to revise the assessment report and BPC opinion in light of the discussions.

7.3. Draft BPC opinions on active chlorine generated from sodium chloride by electrolysis for PT 1, 2, 3, 4 and 5

The Chair welcomed the applicant. The ASOs were allowed to be present during the discussion. The discussion focussed on the items included in the open issues table regarding the comments on the assessment report and the draft BPC opinion.

The eCA briefly introduced the dossiers, informing that the opinions were adopted in 2018 and have been revised upon Commission requests on Art 75 (1) (g) on the ED assessment and on the reference specification of the precursor sodium chloride and the required water quality. The sodium chloride specification, the required water quality and the ED assessment were discussed at WG-I-2020. No conclusion on the ED assessment could be drawn with the available data respect to human and non-target organism, although it was to be noted that there are ED concerns for the impurity chlorate. No conclusion had to be reached since these are back-log dossiers; therefore the ED assessment will be revisited at renewal stage.

There were no other discussions on the assessment report and the BPC opinions were adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 30 July 2020.
- **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 3 July 2020 and publish it on the ECHA website.

7.4. Draft BPC opinions on active chlorine released from hypochlorous acid for PT 1, 2, 3, 4 and 5

The Chair welcomed the applicant. The ASOs were allowed to be present during the discussion. The discussion focussed on the items included in the open issues table regarding the comments on the assessment report and the draft BPC opinion.

The eCA briefly introduced the dossiers, informing that the opinions were adopted in 2018 and have been revised upon Commission request to include the ED assessment. The ED assessment was discussed at WG-I-2020. No conclusion on the ED assessment could be drawn with the available data respect to human and non-target organism, although it was to be noted that there are ED concerns for the impurity chlorate. No conclusion had to be reached since these are back-log dossiers; therefore the ED assessment will be revisited at renewal stage.

The Commission enquired what was the status of the missing data which were already referred in section 2.5 during the BPC discussions in 2018, and for which the Commission had called the applicant during those discussions to already work to submit these data before final conclusions are reached by the BPC. The applicant informed to not have submitted yet the information to the evaluating CA, and plan to submit the information later before the approval date. The Commission expressed its surprise and strong disapointment as full commitment from applicants is expected when they support an active substance, especially on data which should not even be missing in the first place. The Commission called again Member States to be vigilant and ensure that there are no missing data when BPC opinions are delivered.

There was no other discussion as the few comments received were the same as those received for the previously discussed active substance: active chlorine generated from sodium chloride by electrolysis.

The assessment report was agreed and the BPC opinions were adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 30 July 2020.
- **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 3 July 2020 and publish it on the ECHA website.

7.5 Draft BPC opinion on esbiothrin for PT 18

The Chair welcomed the two applicants. The ASOs were allowed to be present during the discussion.

The eCA introduced briefly the dossier related to the active substance and explained that the initial proposal for the Mut. Cat. 2 proposal for the active substance was not accepted by the WG members, the concern of genotoxic photometabolites and the risk assessment of the photometabolites using the Threshold of Toxicological Concern (TTC). Applying the TTC concept leads to the identification of unacceptable risks for non-professional users. Because of these unacceptable risks which cannot be mitigated, the eCA proposes non-approval for esbiothrin.

The applicant presented briefly their position on the issue, regarding the lack of scientific evidence on which the decision was made on the photometabolites. According to the applicant the biological relevance of the critical publications is highly questionable and has several flaws and unknowns. The applicant stressed that there is not enough evidence supporting the decision to identify the photometabolites as genotoxic. Furthermore, based on the low MIC and the absence of in vitro phototoxicity, the weight of evidence would indicate that allethrins do not exhibit photogenotoxic potential under realistic exposure conditions. The applicant submitted prior to the BPC meeting a new study which suggests that the decision on the photometabolites should be reversed and therefore the TTC concept should not be applied.

The eCA explained that all aspects of the concerned critical publication were presented in the CAR. Furthermore, all arguments given by the applicant were already considered by the Working Group members but lead to a different conclusion. The eCA indicated that the

applicant announced during the WG discussions that a new study was going to be performed however this was overruled at the time by the WG, therefore the eCA did not evaluate this new study and did not take it into account in their assessment in line with the BPC procedures. Furthermore even this newly presented data would not give a definitive conclusion according to the eCA. The Commission pointed out that it was important to follow the set procedures for the peer review and that it was too late in the process to take into account a new study. Two members indicated that they were reluctant to base a non-approval decision on literature data and the approach taken for the assessment (TTC), and indicated that they were inclined to accept the newly presented study. However, the majority of the members were against accepting the new study at the BPC stage and supported the assessment and conclusions of the eCA. The eCA reiterated that the WG members based their conclusion on the available data where all arguments, similar to those provided by the applicant during the BPC, were taken into account.

The Commission reminded its recurring comment on the need to improve the quality of the BPC opinions on the section 2.2.3 on the identification of alternatives of substances meeting the subsitution criteria.

All other comments related to the Assessment Report and the BPC opinions indicated in the open issues table were addressed. The assessment report was agreed and the BPC opinion was adopted by consensus. Two members abstained.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 30 July 2020.
- **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 3 July 2020 and publish it on the ECHA website.

8. Union authorisation

8.1 Listing of precautionary statements in section 3 and 5.3 of the SPC

The Chair introduced the document of the SECR. One member stated that the issue raised by the SECR in the document is in fact broader: it concerns not only listing precautionary statements in section 3 and 5.3 but in section 5 in general. This was agreed by the meeting. The proposal from the SECR in the document to incorporate the issue in an on-going CG consultation was agreed.

Actions:

- **SECR:** to amend the document and inform the CG SECR about the agreement.

8.2 Draft BPC opinion on Union authorisation applications for a biocidal product containing propan-2-ol

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

The following issues were discussed and agreed upon:

- The inhalation exposure concentration value in Tier 1 will be corrected.
- The environmental part of the PAR and the BPC opinion will be updated as agreed in the trilateral discussions regarding groundwater assessment.
- Since the applicant has not made confidentiality claims for the wipe specifications, this information can stay in the non-confidential PAR.
- Regarding the risk mitigation measure "Use this products while wearing personal protection such as eye protection, suitable protective clothing and gloves", it was questioned whether protective clothing and gloves are needed for all uses. The applicant explained that since the use of the products is in cleanrooms, protective clothing and gloves are always used. It was nevertheless agreed that the eCA NL will cross-check the risk assessment and will review the need for PPE. If changes will be proposed, NL will consult the SECR.
- A short conclusion of the physico-chemical properties will be added to the BPC opinion.
- Also some other comments regarding clarifications of the wording in the SPC/PAR were agreed upon, and the eCA will update the documents accordingly.

The PAR, SPC and BPC opinion were adopted by consensus.

Actions:

- **Rapporteur**: to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by 29 June 2020.
- **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 3 July 2020.

8.3 Draft BPC opinion on Union authorisation applications for a biocidal product containing 1R-trans phenothrin

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

The following issues were discussed and agreed upon:

- The sentence "*Prior to disinsection, the crew should make sure that the passengers do not have history of allergic reactions toward the a.s. (e.g. asthma)*." will be removed from the PAR and SPC as the practical implementation of this instruction is questionable and does not provide information on the way forward in case of identification of such passengers.

- In the PAR the PEC//PNEC values in the table for the environmental risk characterisation of metabolites in groundwater will be corrected by a factor 10.
- In the SPC, section 4.1.2 and PAR, section 2.1.4.3 will be amended with respect to cats:
  - "lethal" will be replaced by "dangerous";
  - the sentence *"Care must be taken when the product is used in presence of cats. Cats must avoid contact with treated object/area."* will be amended to: *"Care must be taken when the product is used in the presence of cats. Cats must be kept away during treatment."*
- In the SPC, section 4.1.1:
  - the sentence "*Complete elimination of target insects should be attempted in infested areas*." will be removed;
  - "Blocks away" Disinsection - the text will be amended to:
    - This procedure takes place prior to take off after passengers have boarded and the doors have been closed.
    - For disinsection to be effective, the aircraft air conditioning system must be switched off whilst spraying is carried out, and the crew must treat all possible insect harbourages, including toilets, galleys and wardrobes unless these areas have been sprayed together with the flight-deck prior to the boarding.
  - "Top-of-descent" (in-flight spraying) – the sentence:
    - "*Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc)*" will be removed;
    - "Product should not be used for both the pre-flight and in-flight treatment in the same aircraft" will be amended to: *"The product (containing 1R-trans phenothrin) should not be used for both pre-flight and in-flight treatment in the same aircraft"*.
- In the SPC, section 4.1.2 the following sentences:
  - "*Inform the authorisation holder if the treatment is ineffective*" and "*The authorisation holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management*" will be removed as these are regarded as not use-specific RMM, but obligations for the authorisation holder related to resistance management. It is a horizontal policy issue that needs to be further analysed, before included in the SPC or in the terms and conditions of the authorisation;
  - *"Hold can(s) vertically at arm's length. The insecticide aerosol shall be sprayed in the aircraft directing the nozzle of the aerosol dispenser at an angle of approximate 45° towards the ceiling throughout. Spray uniformly through whole area. The spray should be directed slightly behind the user"* were considered as not use-specific RMMs and will be moved to section 4.1.1.
  - "*Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice*" will be moved to section 4.1.3.
- In the SPC, section 6 - the two paragraphs were considered as not related to "other information" about the product as these describe general procedures that need to

be followed by the crew when disinsection using biocidal products is taking place. These two paragraphs will be removed from the SPC.

- In the BPC opinion, section Animal Health - the proposed risk mitigation measure *"lethal"* will be replaced by *"dangerous"*. PAR and SPC will be modified accordingly.

The PAR, SPC and BPC opinion were adopted by consensus.

Actions:

- **Rapporteur**: to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by 29 June 2020.
- **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 3 July 2020.

8.4 Draft BPC opinion on Union authorisation applications for a product family containing permethrin

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

The following issues were discussed and agreed upon:

- The application frequency will be harmonised between human health and environment risk mitigation measures in the PAR.
- The sentence "potentially carrying vector-borne diseases in order to ensure health protection" in the PAR will be deleted.
- The PAR will be checked for remaining inconsistencies in the concentrations of technical active substance and pure permethrin for exposure assessment and for the values used for the leachable fraction and dermal absorption. The applicant referred to the dermal absorption value which was changed during the peer review in an ad hoc follow-up from 5.7 % to 50 %. The default value from EFSA guidance (2017) needed to be used, since no study conducted on dermal absorption for this product was provided. Due to this change the risk to human health became unacceptable. The applicant stated that the generation of a new study should be accepted at this stage of the process. However, the BPC agreed that at this stage this cannot be accepted wheras in addition this cannot be considered without a Working Group agreement.
- Two letters from the applicant were included in the open issues table and the applicant presented their views on the process leading to the proposal to not authorise the biocidal product.
- Comparison of Insecticide Textile Contact to another authorised product containing permethrin was presented by a member. It was concluded that the application rates and thus risks are much higher in the present product compared to the already authorised product. The BPC agreed with the conclusions reached that the use of the biocidal product leads to unacceptable risks which cannot be mitigated.

The PAR, SPC and BPC opinion were adopted by consensus.

Actions:

- **Rapporteur**: to revise the product assessment report (PAR) in accordance with the discussions in the BPC and submit to the SECR by 29 June 2020.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion and final PAR to COM by 3 July 2020.

8.5 Draft BPC opinion on Union authorisation applications for a product family containing hydrogen peroxide

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

The PAR, SPC and BPC opinion were adopted by consensus.

Actions:

- **Rapporteur**: to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by 29 June 2020.
- **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 3 July 2020.

9. Any Other Business

9.1 Harmonised List of Endpoints for pyrethroid metabolites – environmental hazards

This agenda item was not discussed: a written procedure will be initated.

9.2 Revision ECHA Guidance Volume III Human Health Information Requirements

This agenda item was not discussed and was postponed to the next BPC meeting.

9.3 Sensitisers and quantitative risk assessment (QRA)

This agenda item was not discussed: a written procedure will be initated.

10. Agreement of the action points and conclusions

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

Part II - Main conclusions and action points

Main conclusions and action points

Agreed at the 35th meeting of BPC
16-18 June 2020

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-34	
The revised version of the minutes of BPC-34 was agreed as proposed.	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website.
Item 5 – Administrative issues	
-	**-**
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 **26 June 2020.**
Item 7 - Applications for approval of active substances	
7.1 Draft BPC opinion on carbox dioxide generated from propane, butane or a mixture of both by combustion for PT 19	
The BPC adopted by consensus the opinion for 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 2020.** **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 **3 July 2020** and publish it on the ECHA website.

7.2 Draft BPC opinion on C(M)IT for PT 6	
The BPC did not adopt the draft opinion for the approval of the active substance.	**Rapporteur:** to revise the assessment report and BPC opinion in light of the discussions.
7.3 Draft BPC opinion active chlorine generated from sodium chloride by electrolysis for PT 1, 2, 3, 4 and 5	
The BPC adopted by consensus the opinions for 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 2020.** **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 **3 July 2020** and publish it on the ECHA website.
7.4 Draft BPC opinion active chlorine released from hypochlorous acid for PT 1, 2, 3, 4 and 5	
The BPC adopted by consensus the opinions for 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 2020.** **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 **3 July 2020** and publish it on the ECHA website.
7.5 Draft BPC opinion Esbiothrin for PT 18	
The BPC adopted by consensus the opinion for the non-approval of the active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **30 July 2020.** **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 **3 July 2020** and publish it on the ECHA website.
Item 8 – Union authorisation	
8.1 Listing of precautionary statements in section 3 and 5.3 of the SPC	
The BPC agreed the document, concluding however that the issue relates not only to section 5.3 but section 5 in general.	**SECR:** to revise the document and inform the CG SECR about the agreement.

8.2 Draft BPC opinion on Union authorisation applications for a product family containing propan-2-ol	
The BPC adopted by consensus the opinion for the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **29 June 2020**. **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 **3 July 2020**.
8.3 Draft BPC opinion on Union authorisation applications for a product family containing 1R-trans-phenothrin	
The BPC adopted by consensus the opinion for the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **29 June 2020**. **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 **3 July 2020**.
8.4 Draft BPC opinion on Union authorisation applications for a product family containing permethrin	
The BPC adopted by consensus the opinion for the non-authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) in accordance with the discussions in the BPC and submit to the SECR by **29 June 2020**. **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion and final PAR to COM by **3 July 2020**.
8.5 Draft BPC opinion on Union authorisation applications for a product family containing hydrogen peroxide	
The BPC adopted by consensus the opinion for the authorisation of an application for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **29 June 2020**. **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 **3 July 2020**.

Item 9 –Any other business	
9.1 Harmonised List of Endpoints for pyrethroid metabolites – environmental hazards	
Agenda point moved to the next meeting	-
9.2 Revision ECHA Guidance Volume III Human Health Information Requirements	
Agenda point moved to the next meeting	-
9.3 Sensitisers and quantitative risk assessment (QRA)	
Agenda point moved to the next meeting	-

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Part III - List of Attendees

Members	GKILPATHI Dimitra (EL)
BALDASSARRI Lucilla (IT)	GOUR Annabelle (FR)
BORGES Teresa (PT)	HYVARINEN Tuija (FI)
BRANDT Charlotte (BE)	IGAUNE Ieva (LV)
BROVKINA Julija (LV)	JARRETY Helene (BE)
CARBERRY Stephen (IE)	KADIKIS Normundus (LV)
CEBASEK Petra (SI)	KALKERS Lucas (NL)
CHEZEAU Aurelie (FR)	KRAFTE Kristine (LV)
DRAGOIU Simona (RO)	KRUIDHOF Sabine (NL)
GONZALEZ MARQUEZ Maria Luisa (ES)	LEPAGE Anne (BE)
GREGERSEN Nina Falk (DK)	MEZULE Linda (LV)
HAHLBECK Edda (SE)	MUIJS Barry (NL)
HAKAITE Palmira (LT)	OLHA Roman (SK)
JAGER Stefanie (DE)	PUTNA-NIMANE Ieva (LV)
JOHN Nina (AT)	RIFFAUT Lea (FR) *
LANS Martine (NL)	RUDZOK Susanne (DE)
MERISTE Anu (EE)	SCHNEIDER Heiko (DE)
MIKOLAS Jan (CZ)	TORDOIR Charlotte (BE)
MIKOLASKOVA Denisa (SK)	VAN NOORLOOS Brigitte (NL)
RANDALL Marit (NO)	WARMERDAM Sonja (NL)
VAGIAS Vasileios (EL)	WEINHEIMER Viola (DE)
ZIGRAND Jeff (LU)	WELTEN Angelique (NL)
Alternate members	
HAMALAINEN Anna-Maija (FI)	
SZENTGYORGYI Timea (HU)	**European Commission**
PYTHON François (CH)	CAINZOS GARCIA Marta (DG SANTE)
Advisers	CHATELIN Ludovic (DG SANTE)
ASK BJÖRNBERG Karolin (SE)	DELVAUX Vincent (DG SANTE)
BLOCH Carsten (DE)	GKINIS Georgios (DG SANTE)
BOITIER Caroline (FR) *	NAGTZAAM Martinus (DG SANTE)
BOS Carina (NL)	
EHNI Markus (DE)	**Invited experts**
ENSCH Svenja (LU)	HUSZAL Sylwester (PL)

Accredited Stakeholder Observers	ECHA Staff
CAZELLE Elodie	DAMSTEN Micaela
CINGOTTI Natcha	HONKA ANNI
DROHMANN Dieter	JANKA Adel
ERGEN Vincent	JARDIN Helene
KJELLBERG Håkan	KREBS Bernhard
MASSEL Arnaud	KURONEN Terhi
MIHAI Camelia	PRIHA Outi
VAN BERLO Boris	RAULIO Mari
	SAEZ RIBAS Monica
Applicants	SZYMANKIEWICZ Katarzyna
Aero-Sense	VAN DE PLASSCHE Erik
Aqualution Systems Ltd	VAN GALEN Joost
DAKEM S.A.	VASILEVA KATYA
Ecolab Deutschland GmbH	
ENDURA S.p.A.	**Apologies**
Exponent International	CY
Sumitomo Chemical (UK) Plc	HR
THOR GmbH	MT
Veltek Associates Inc. Europe	

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-35

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-35 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2	BPC-A-35-2020_rev2	Draft agenda	
4	BPC-M-34-2020	Draft minutes from BPC-34	
5.1	-	Administrative issues and report from the other Committees	
6.1	BPC-35-2020-01 BPC-35-2020-02 BPC-35-2020-03 BPC-35-2020-04	BPC Work Programme for active substance approval, Union authorisation, ED assessment and outlook for BPC	
8.1	BPC-35-2020-18	Listing of precautionary statements in section 3 and 5.3 of the SPC	
9.1	BPC-35-2020-23	Harmonised List of Endpoints for pyrethroid metabolites – environmental hazards	
9.2	BPC-35-2020-24	Revision ECHA Guidance Volume III Human Health Information Requirements	
9.3	BPC-35-2020-25	Sensitisers and quantitative risk assessment (QRA)	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.1	BPC-35-2020-05A	Carbon dioxide generated from propane, butane or a mixture of both by combustion PT 19	Draft BPC opinion
	BPC-35-2020-05B		Assessment report
	BPC-35-2020-05C		Open issues
7.2	BPC-35-2020-06A	C(M)IT PT 6	Draft BPC opinion
	BPC-35-2020-06B		Assessment report
	BPC-35-2020-06C		Open issues
	BPC-35-2020-06D		FR position paper
	BPC-35-2020-07A		Draft BPC opinion

7.3	BPC-35-2020-07B	Active chlorine generated from sodium chloride by electrolysis PT 1	Assessment report
	BPC-35-2020-07C		Open issues
	BPC-35-2020-08A	Active chlorine generated from sodium chloride by electrolysis PT 2	Draft BPC opinion
	BPC-35-2020-08B		Assessment report
	BPC-35-2020-07C		Open issues
	BPC-35-2020-09A	Active chlorine generated from sodium chloride by electrolysis PT 3	Draft BPC opinion
	BPC-35-2020-09B		Assessment report
	BPC-35-2020-07C		Open issues
	BPC-35-2020-10A	Active chlorine generated from sodium chloride by electrolysis PT 4	Draft BPC opinion
	BPC-35-2020-10B		Assessment report
	BPC-35-2020-07C		Open issues
	BPC-35-2020-11A	Active chlorine generated from sodium chloride by electrolysis PT 5	Draft BPC opinion
	BPC-35-2020-11B		Assessment report
	BPC-35-2020-07C		Open issues
7.4	BPC-35-2020-12A	Active chlorine released from hypochlorous acid PT 1	Draft BPC opinion
	BPC-35-2020-12B		Assessment report
	BPC-35-2020-12C		Open issues
	BPC-35-2020-13A	Active chlorine released from hypochlorous acid PT 2	Draft BPC opinion
	BPC-35-2020-13B		Assessment report
	BPC-35-2020-12C		Open issues
	BPC-35-2020-14A	Active chlorine released from hypochlorous acid PT 3	Draft BPC opinion
	BPC-35-2020-14B		Assessment report
	BPC-35-2020-12C		Open issues
	BPC-35-2020-15A	Active chlorine released from hypochlorous acid PT 4	Draft BPC opinion
	BPC-35-2020-15B		Assessment report
	BPC-35-2020-12C		Open issues
	BPC-35-2020-16A	Active chlorine released from hypochlorous acid PT 5	Draft BPC opinion
	BPC-35-2020-16B		Assessment report
	BPC-35-2020-12C		Open issues
7.5	BPC-35-2020-17A	Esbiothrin PT 18	Draft BPC opinion
	BPC-35-2020-17B		Assessment report
	BPC-35-2020-17C		Open issues
8.2	BPC-35-2020-19A	UA: product family containing propan-2-ol	Draft BPC opinion
	BPC-35-2020-19B		SPC
	BPC-35-2020-19C		PAR
	BPC-35-2020-19C1		Conf annex to PAR

	BPC-35-2020-19D		Open issues
8.3	BPC-35-2020-20A	UA: product family containing 1R-trans phenothrin	Draft BPC opinion
	BPC-35-2020-20B		SPC
	BPC-35-2020-20C		PAR
	BPC-35-2020-20C1		Conf annex to PAR
	BPC-35-2020-20D		Open issues
8.4	BPC-35-2020-21A	UA: product family containing permethrin	Draft BPC opinion
	BPC-35-2020-21C		PAR
	BPC-35-2020-21C1		Conf annex to PAR
	BPC-35-2020-21D		Open issues
8.5	BPC-35-2020-22A	UA: product family containing hydrogen peroxide	Draft BPC opinion
	BPC-35-2020-22B		SPC
	BPC-35-2020-22C		PAR
	BPC-35-2020-22C1		Conf annex to PAR
	BPC-35-2020-22D		Open issues

5 June 2020
BPC-A-35-2020_rev2

Draft agenda

35th meeting of the Biocidal Products Committee (BPC)

16 - 18 June 2020

Meeting is held virtually via WebEx

Starts on 16 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-35-2020

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-34

BPC-M-34-2020

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-35-2020-01; BPC-35-2020-02; BPC-35-2020-03; BPC-35-2020-04

For information

7. – Applications for approval of active substances*

7.1. Draft BPC opinion on carbon dioxide generated from propane, butane or a mixture of both by combustion for PT 19

Previous discussion: WG-I-2020

BPC-35-2020-05A, B, C
For adoption

7.2. Draft BPC opinion on C(M)IT for PT 6

Previous discussion: WG–I-2020

BPC-35-2020-06A, B, C
For adoption

7.3. Draft BPC opinions on active chlorine generated from sodium chloride by electrolysis for PT 1, 2, 3, 4 and 5

Previous discussions: BPC-25; WG-I-2020

PT 1: BPC-35-2020-07A, B, C
PT 2: BPC-35-2020-08A, B, C
PT 3: BPC-35-2020-09A, B, C
PT 4: BPC-35-2020-10A, B, C
PT 5: BPC-35-2020-11A, B, C
For adoption

7.4. Draft BPC opinions on active chlorine released from hypochlorous acid for PT 1, 2, 3, 4 and 5

Previous discussions: BPC-25; WG-I-2020

PT 1: BPC-35-2020-12A, B, C
PT 2: BPC-35-2020-13A, B, C
PT 3: BPC-35-2020-14A, B, C
PT 4: BPC-35-2020-15A, B, C
PT 5: BPC-35-2020-16A, B, C
For adoption

7.5. Draft BPC opinion on esbiothrin for PT 18

Previous discussions: WG-III-2017, WG–V-2018

BPC-35-2020-17A, B, C
For adoption

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

8. – Union authorisation**

8.1 Listing of precautionary statements in section 3 and 5.3 of the SPC

BPC-35-2020-18

For agreement

8.2 Draft BPC opinion on Union authorisation applications for a product family containing propan-2-ol

Previous discussion: WG-I-2020

BPC-35-2020-19A, B, C, D

For adoption

8.3 Draft BPC opinion on Union authorisation applications for a product family containing 1R-trans phenothrin

Previous discussion: WG-I-2020

BPC-35-2020-20A, B, C, D

For adoption

8.4 Draft BPC opinion on Union authorisation applications for a product family containing permethrin

Previous discussion: WG-I-2020

BPC-35-2020-21A, B, C, D

For adoption

8.5 Draft BPC opinion on Union authorisation applications for a product family containing hydrogen peroxide

Previous discussions: WG-II-2019; WG-V-2019; WG-I-2020

BPC-35-2020-22A, B, C, D

For adoption

9. - Any other business

9.1 Harmonised List of Endpoints for pyrethroid metabolites – environmental hazards

BPC-35-2020-23

For agreement

9.2 Revision ECHA Guidance Volume III Human Health Information Requirements

BPC-35-2020-24

For information

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

9.3 Sensitisers and quantitative risk assessment (QRA)

BPC-35-2020-25

For discussion

10. - Action points and conclusions

Via written procedure

Provisional time schedule for the

35th meeting of the Biocidal Products Committee (BPC)

Virtual meeting via WebEx

16 June 2020: starts at 10:30; 18 June 2020 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 16 June: morning session (starts at 10:30)

Items 1-5	Opening items and administrative issues
Item 6.1	BPC Work Programme for active substance approval, BPC Work Programme for Union authorisation, Outlook for BPC, Status ED assessment for active substances
Item 7.1	Draft BPC opinion on carbon dioxide generated from propane, butane or a mixture of both by combustion for PT 19
Item 7.2	Draft BPC opinion on C(M)IT for PT 6

Tuesday 16 June: afternoon session

Item 7.2	(cont'd)
Item 7.3	Draft BPC opinions on active chlorine generated from sodium chloride by electrolysis for PT 1, 2, 3, 4 and 5
Item 7.4	Draft BPC opinions on active chlorine released from hypochlorous acid for PT 1, 2, 3, 4 and 5
Item 7.5	Draft BPC opinion on esbiothrin for PT 18

Wednesday 17 June: morning session (starts at 10:30)

Item 8.1	Listing of precautionary statements in section 3 and 5.3 of the SPC
Item 8.2	Draft BPC opinion on Union authorisation applications for a product family containing propan-2-ol
Item 8.3	Draft BPC opinion on Union authorisation applications for a product family containing 1R-trans phenothrin

Wednesday 17 June: afternoon session

Item 8.3	(cont'd)
Item 8.4	Draft BPC opinion on Union authorisation applications for a product family containing permethrin

Thursday 18 June: morning session (starts at 10:30)

Item 8.5	Draft BPC opinion on Union authorisation applications for a product family containing hydrogen peroxide
Item 9.1	Harmonised List of Endpoints for pyrethroid metabolites – environmental hazards
Item 9.2	Revision ECHA Guidance Volume III Human Health Information Requirements
Item 9.3	Sensitisers and quantitative risk assessment (QRA)
Item 10	Action points and conclusions

End of meeting

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