16 June 2020

BPC-M-34-2020

Minutes of the 34th meeting of the Biocidal Products Committee (BPC)

4-5 March 2020

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chairman of the Biocidal Products Committee (BPC) welcomed the participants to the 34th BPC meeting which took place for the first time in the new Conference Centre of ECHA.

Regarding the BPC membership, the Chairman stated that there is a new appointed BPC member from Cyprus; Andreas Hadjigeorgiou, and a new appointed alternate BPC member from Cyprus as well; Nikos Elia.

The Chairman then informed the BPC members of the participation of 21 members, including one alternate member, one member attending remotely and one member whose official nomination is pending. In addition, Poland was represented by an invited expert. Several members could not participate because of the Corona-virus epidemic.

9 advisers and 1 representative from an accredited stakeholder organisation (ASO) were present at the meeting. A representative from the European Commission attended the meeting, and other representative from the European Commission attended via Webex.

Applicants were invited and present for their specific substances under agenda item 7, excluding the agenda point 7.2 where the applicant was not present at the meeting, and 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 Chairman introduced the final draft agenda (BPC-A-34-2020_rev1) and invited any additional items. No additional items were presented and the agenda was adopted. The final version of the agenda will be uploaded to the BPC CIRCABC IG as part of the meeting minutes.

The Chairman 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 Chairman 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-33

The revised draft minutes from BPC-33 (BPC-M-33-2019), incorporating the comments received, were agreed.

The Chairman noted that most of the actions from BPC-33 have been carried out:

- The revised opinion templates for active substance approval and for union authorisation were finalised by the SECR and made available after the meeting to the BPC via CIRCA BC. The documents on “Introducing new data during the peer review phase for Union Authorisation applications” and the revised “Procedure for the linguistic review of the SPC for Union Authorisation applications” were published on the BPC page of the ECHA web-site.
- The amended opinion on DBNPA PT 4 was published on the ECHA website.

The Chairman 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 March meeting. This item will subsequently come back at the appropriate BPC meeting.

Actions:

- **SECR:** to upload the agreed minutes from BPC-33 to the BPC CIRCABC IG and to the ECHA website after the meeting.

5. Administrative issues

5.1 Housekeeping issues

The SECR highlighted the key aspects of the housekeeping rules including the safety and security rules.

6. Work Programme for BPC

6.1 BPC Work Programme for active substance approval

6.2 BPC Work Programme for Union Authorisation

6.3 Outlook for the BPC

The Chairman 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 Chairman stated that:

- For active substance approval 21 opinions are to be adopted in 2020 of which 18 are for the Review Programme and 10 are returned opinions via Article 75(1)(g) for ED assessment.
- For Union authorisation the number of opinions to be adopted in 2020 is 17. The Chairman referred to agenda item 8.1 for a further discussion.
- Furthermore the outlook for 2020 contains 1 Article 75(1)(g) request on which the meeting was informed in December (active chlorine generated via electrolysis).

Maybe some Article 38 opinions will be requested in addition. Overall the workload for 2020 seems to be manageable considering the four meetings scheduled.

- The SECR expressed its concerns with respect to the delays observed in the active substance approval and Union authorisation process.

The Chairman asked the eCAs being rapporteur for active substances or Union authorisations scheduled for discussion at the June 2020 BPC meeting (BPC-35), to confirm this planning to the SECR by 30 April 2020.

Similarly to previous meetings, the Commission expressed concerns on the general progress and reminded that Member States must implement the actions agreed at the CA meeting in the past years, 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 1st September 2013. Reference was also made to the agreement reached at the last CA meeting on the ECHA Action Plan on Active Substance Approval which must now be implemented by all parties.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by **13 March 2020**.

6.4 Status ED assessment for active substances

The SECR presented an overview on the status of the ED assessment of active substances.

The Commission reiterated its request made at the last BPC meeting that the status report should cover all active substance dossiers under review, so that the progress on all dossiers on ED assessment is monitored and reported. This will be discussed bilaterally between ECHA and the Commission.

7. Applications for approval of active substances

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

The Chairman stated that this document had not been changed compared to the previous version.

7.2 Draft BPC opinion on chlorophene for PT 2

The Chairman informed that the applicant was not present during the discussion. 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 received on the updated CAR and the draft BPC opinion. All conclusions are recorded in the open issue table.

The eCA informed that after the finalisation of the CAR at BPC-22, the eCA was informed by the US EPA that the key 90 day dog study in the dossier had been deemed invalid by the US EPA as the study had been conducted at a testing laboratory having falsified data reports on several chemicals. This finding lead to a revision of the human health risk

assessment in which the study was removed from the dossier. This resulted in a data gap for the subchroninc toxicity endpoint for the second animal species.

Given that the data gap was identified at a very late stage (i.e. after the BPC discussion), the eCA suggested to apply an additional AF in the AEL setting to compensate for the incomplete data package in order to be able to finalise the risk assessment for chlorophene.

The revised risk assessment was discussed at the Human Health WG V 2019 where an unacceptable risk to human health was identified for small scale sanitary non-professional use due to the local effects of the reference product. An unacceptable risk was also identified for the professional professional cleaning personnel as well as professional health care workers for systemic effects. In addition, unacceptable risk was identified for the environment.

The Committee also noted that the interim criteria in Article 5(3) for identifying chlorophene as an active substance with endocrine disrupting properties are no longer relevant. Therefore the analysis of alternatives and the section on identification of alternatives will be removed from the BPC opinion and be included in the AR.

All the issues indicated in the open issues table were discussed and agreed by the Committee. The BPC adopted by consensus the opinion for the non-approval of the active substance/PT combination.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 17 April 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 24 March 2020 and publish it on the ECHA website.

7.3. Draft BPC opinion on glyoxal PT 2, 3 and 4

The Chairman 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 summarised that glyoxal is an existing substance supported for PT 2, 3 and 4 only for professional uses. The initial dossier was submitted in 2009 and revised in 2016. The draft CAR was submitted to ECHA in 2019 and discussed at the Working Group IV 2019.

The BPC discussions focussed on several issues.

The validity of the analytical methods submitted for air, water, and food and/or feedstuff, mainly the LOQ, in the absence of validated background concentrations due to its high variability in different compartments, the lower concentrations for natural occurring glyoxal and the impossibility to distinguish between the biocidal use from natural sources. There were some discussions on the need for those methods given the automated conditions of the processes; the absence of a MRL where a rinsing step is required to ensure no residues. The methods were considered necessary by the BPC for monitoring in

the mentioned compartments, including the food and feedstuff after the rinsing step. The BPC concluded on a stepwise approach, the eCA to first check and discuss the background concentrations after data submission by the applicant, and then the need to further validate the analytical methods.

The impossibility to conclude, by the Human Health WG, on the carcinogenicity and consequently on the exclusion criterion either, due to insufficient information being available lead to discussions on how to proceed. It was concluded that the eCA and applicant may further discuss on the furter data required to refine the assessment. Glyoxal is classified under CLP as a Muta Cat 2, while there is no classification for carcinogenicity, so a qualitative instead of quantitative risk assessment was performed, which lead to a very restrictive approval proposal (automated systems; CIP; PPE; requirements for adequate rinsing after use). However, especially secondary exposure cannot completely be excluded even with this very restrictive measures. Furthermore, it was agreed that further guidance needs to be developed by the Human Health WG on what contains a qualitative risk assessment and guidance on how to perform the required rinsing study.

A discussion took place on the fact that the submitted data do not allow to conclude whether glyoxal may also have to be classified as Muta 1 (A or B) as the current wording of Annex II of the BPR does not foresee to perform further in-vivo genotoxicity testing in case the active substance is already classified as Muta 2. It was agreed to include in the Assessment Report that the data requirements of Annex II regarding this endpoint are currently amended to enable concluding on the exclusion criteria.

There were discussions on the requirement of PPE on top of the automation requirement. Some members stated that there is in principle a data gap on the carcinogencity endpoint, referring to other evaluations where such a data gap was indentified but addressed before the adoption of the BPC opinion. Finally, the majority supported the approval proposals given the restrictive conditions and the possibility indicated by the Commission to reduce the approval period.

All the issues indicated in the open issues table were discussed and agreed by the Committee. The assessment report and BPC opinions were adopted by majority, with a minority position from SE and an abstention from DE.

The Commission indicated that, considering the data gap on carcinogenicity data identified during the peer review, and the fact that the substance is classified Mutagen Category 2 and no threshold was identified, it will carefully consider the BPC opinion when it will prepare its draft decision.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 17 April 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.
- **Member (SE):** to submit the minority position by 11 March 2020.
- **SECR:** to forward the adopted opinion to COM by 24 March 2020 and publish it on the ECHA website.

7.4 Draft BPC opinion on Reaction mass of peracetic acid and peroxyoctanoic acid for PT 2, 3 and 4

The Chairman welcomed the applicant. The ASOs were not allowed to be present during the discussion. The discussion focussed on the items included in the open issues table regarding the comments received on the assessment report and the draft BPC opinion. All conclusions are recorded 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 17 April 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 24 March 2020 and publish it on the ECHA website.

8. Union authorisation

8.1 Update on Union authorisation

An update on Union authorisation was given by the SECR: i) an overview of the current status of the UA-APP and UA-BBP applications in ECHA's pipeline; ii) procedural issues; iii) on-going coordination activities by ECHA on coordination of the Union authorisation process; iv) SPC translation process.

Actions:

- **SECR:** to upload the presentation on the BPC CIRCABC IG.
- **Members:** to provide feedback on the accordance check before 1 April 2020.

8.2 Combining uses of different biocidal products in a BPF for exposure assessment

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

The Chairman welcomed the applicant. The ASOs were allowed to be present during the discussion. The discussion focused on the items included in the open issues table regarding the comments received on the draft PAR, draft SPC and the draft BPC opinion.

The following issues were discussed:

- The use instruction "make sure to wet surfaces completely" was considered sufficient and easily understandable for the non-professional user; thus the number of wipes used per m^2 does not need to be stated.

- The amount of soaking solution per wipe was considered as confidential business information, and should be moved into the Confidential Annex of the PAR. The specific picture of the packaging "revolver bag" showing the brand name was agreed to be replaced by a more general picture in the PAR.
- A discussion took place on whether P-statements triggered by both the CLP legislation and risk assessment should be listed both in section 3 *Hazard and precautionary statements* and in section 5 *General directions of use* of the SPC. The eCA was of the opinion that if measures are trigged by the risk assessment, they need to be added to section 5 avoiding that they do not appear on the label, as the choice which P-statement appears on the label is the responsibility of the applicant. In addition, the P-statement has to be added to section 3 if it is required according to the CLP regulation So in these cases the phrases should be added to both sections even if it means repetition. It was agreed that the SPC does not need to be amended regarding repetitive P-sentences.
- On more general terms the Chair noted that varying approaches have been followed for previous UA applications, and one MS stated that the enforcement authorities are not in favour of having repetitive information in the SPC. SE has initiated an e-consultation for CG on harmonisation of the first aid measures, relevant for Section 5.3 of the SPC, which is planned to be discussed at CG in May. It was agreed to open a Newsgroup on this issue, the outcome of which will be discussed at the next BPC meeting.
- In addition it was agreed to amend the use-specific risk mitigation measures for meta SPCs 1, 3 and 7, and to remove unclear expressions using "if required" from application frequency sections of the SPC.
- For the BPC opinion it was agreed to amend the general introduction of the product to include the PTs and category of users, and to state that a concern for endocrine-disrupting properties was identified for a co-formulant. For physico-chemical properties a conclusion on the analytical methods will be added, indicated parts of the human health section will be amended to be in line with the PAR, and more information will be added to the section on environment.
- Also some other comments regarding alignment of information in PAR, SPC and the BPC opinion were discussed, and the eCA will update the documents as agreed.

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 20 March 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 1 April 2020.

8.4 Draft BPC opinion on Union authorisation applications for a product family containing CMIT/MIT

The Chairman welcomed the applicant. The ASOs were allowed to be present during the discussion. The eCA introduced briefly the dossier related to a biocidal product family containing C(M)IT/MIT for preservation of fuels during storage.

The BPC discussion focussed on the first item included in the open issues table concerning the emission of dioxins formed during combustion in motors of for example cars, planes and ships due to the presence of C(M)IT as it contains chlorine. The eCA acknowledged that the formation of dioxin during the combustion of fuels is possible. However, the eCA pointed out that it was not feasible to make any risk assessment and to conclude on this issue as this was not addressed in the application so no data were available in the dossier. The Chairman explained that unfortunately ECHA became aware of this issue late in the process because this issue was closed before the WG meetings. Thus, the point about dioxin formation during combustion in motors was up to now not discussed during the peer-review phase. A document containing preliminary technical and regulatory information prepeared by SECR was sent to the BPC members a few days before the meeting. Also, members were also asked to inform the SECR about existing national legislation to which some responded. The Chairman pointed out that the main point for the BPC discussion is to define what to do in terms of the BPC opinion.

COM noted also that it was regrettable this issue was not discussed further during the evaluation phase and the WG meetings. COM informed the BPC members that one member notified COM of a national measure prohibiting that the fuels for cars contain additives with chlorine or bromine on its market. As a consequence the concerned member asked not to authorise this product or otherwise required a derogation. COM asked to the concerned member whether their national measures prohibiting that fuels for cars containing additives with chlorine or bromine was the result of risk identified based on an assessment made on existing data and calculations, or of the application of a precautionary approach. COM indicated that it would be helpful for the decision making process to have some quantification of the level of dioxin emission or of the quantity of dioxin formed compared to the volume of fuels treated, and a comparison with emissions coming from other sources than CMIT/MIT.

The concerned member clarified that despite the existing national measure concerning only motor vehicles on roads, there is no threshold value regarding dioxins emitted. Thus, using a precautionary approach on this issue was considered by the member as the appropriate way to meet the objective of the POP Convention. This member stated they have a general objection to authorise the product because of the possible emission of dioxin due to the use of this product, irrespective of the amount of dioxins emitted. They are of the opinion that the product shall not be authorised and in any case require a derogation.

One other member indicated that their point about their national measure which includes limits for chlorinated substances in fuels was reported in the open issues table. The member explained that some further internal calculations demonstrated that the product would comply with the threshold defined in their national legislation so with respect to this aspect there is no objection for them to authorise the product. The member also indicated

– following a question from COM - there is one similar product which is authorised for the same use at national level.

One other member commented that while there is no specific legislation for chlorine compounds added in fuels at national level, they refer to EU legislation on fuels. However, the member confirmed explicitly that it has no objection to authorise the product. Another member expressed also regrets that the dioxin formation issue was not discussed at the WG level. The member indicated that some investigations were made regarding national legislation but nothing was found. However, they expressed strong concerns about the issue of dioxins formation in general stemming from the POP Regulation and Convention, which indicates that emission should be avoided. One other member indicated the issue should be dealt with within the POP Regulation and Convention and argued to postpone the discussion to enable discussions at WG level. Postponing the discussion was not considered an option by the SECR due to the exceedance of the 3 year period after the approval date of 1 July 2017 for C(M)IT/MIT in PT 06.

A discussion took place on the question of the quantification of the formation of dioxins and the possibility of a risk assessment, for which WG discussions would be needed. The Chairman pointed out that there are only estimates showing a low level of emission as mentioned in the document provided by the SECR before the meeting. However, this document has not been peer reviewed. The Applicant indicated that the topic about dioxins formation should not have been brought to the BPC in the context of this Union authorisation. The Applicant expressed the opinion that the reduction of emission of dioxin is more in the scope of the POP Convention than of the BPR. In addition, the Applicant informed during the meeting about some theoretical calculations using studies and the existing literature to support the quantification of the level of dioxin formation. The Applicant concluded that the level of dioxin formation for motor vehicles on roads will be extremely low based on the sales of the biocidal product for fuels. COM confirmed that in case the opinion is adopted, the concerns on dioxin formation will have to be addressed. In particular, the question of the quantification of the dioxin formation and associated risk assessment will probably be raised in the decision making process. Furthermore, in reply to the Applicant's comment, COM clarified that the BPC is legitimate to discuss the issue of the dioxin formation and highlighted that it should have been done even before as already indicated. From a legal point of view, COM pointed out there will be a need to discuss whether authorising a product that would generate dioxins would be in line with the POP Convention. COM acknowledged that the Applicant may now have some data, however they have not been peer reviewed. It was also mentioned – among others by the SECR – that performing a risk assessment will be very difficult as no data (for example content of C(M)IT/MIT in fuels after removal of water in the storage tanks; conversion and emission of dioxins from combustion of present day fuels for cars, airplanes and ships) and no available scenario.

It was discussed if the issue on dioxin formation should be included – and if so how – in the opinion. As the issue was not discussed at technical and scientific level in the Working Groups and therefore no informed decision or conclusion could be reached by the BPC, and because postponing the adoption would lead to the exceedance of the 3 year period set in Atricle 89 of the BPR, it was decided to not address the issue in the opinion. Instead, it was decided that the SECR will describe the issue – reflecting also the BPC discussion – in an accompanying letter when submitting the opinion to COM.

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

The BPC opinion was adopted by majority. One member filed a minority opinion.

Actions:

- **Rapporteur**: to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by 20 March 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.
- **Member (DE):** to submit the minority position by 12 March 2020.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by 1 April 2020.

8.5 Draft BPC opinion on Union authorisation applications for a product family containing peracetic acid

The Chairman welcomed the applicant. The ASOs were allowed to be present during the discussion. The Chairman explained to the BPC members that this application was taken over by the new eCA BE from the UK after 31 January 2020.

The discussion focussed on the items included in the open issues table regarding the comments received on the draft PAR, SPC and the draft BPC opinion. All conclusions are recorded in the open issue table. The summary of the main discussed points is included here:

- During the meeting it was clarified that that the release area for trigger spray to be used was confirmed to be 0.5 m^2 by HH WG e-consultation. Thus the BPC members agreed to include the following RMM: “The product must only be applied for disinfection of small surfaces."
- In relation to the human health exposure assessment it was noted that decision was taken during the WG V 2019: here it was decided that, due to the timing of the dossier, it was not necessary to take Recommendation 16 of the ad-hoc Working Group on Human Exposure into account. The WG also agreed to use the evaporation model in Consexpo. This approach was followed by the eCA BE and supported by the BPC members.
- The RMMs applied for Use 1 were clarified. In particular, it was noted that a ventilation rate of at least 20/hr is mandatory when handling the product.
- The RMMs applied for Use 2 were clarified by the eCA BE, i.e., there is no need to apply RPE since technical mitigation measures are applied.
- The eCA provided a clarification on the qualitative and quantitative composition of the products. This clarification will be included in the updated confidential annex of the PAR.

- The term “appropriate material” should be clarified through the PAR and SPC: it was decided to include the terms “suitable cleanroom wipe” or “suitable cleanroom mop”. The applicant clarified that there are specific wipes and mops which are produced to be used in clean room conditions in order to maintain a high clean room requirements and reduce unnecessary use of the disinfectant product.
- The documents will be updated and all uses will be combined in one metaSPC.
- The question was raised whether this should be a single product authorisation or biocidal product family authorisation. The members were asked to provide their input directly to the Commission.
- Several other comments were noted in order to ensure constituency though the document and align information in all documents PAR, SPC and the BPC onion. The eCA BE will updated documents accordingly.

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 20 March 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 1 April 2020.
- **Members**: to send their experience on similar cases (See comment 60 of the open issue table) to the COM by 26 March 2020.

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

The chair welcomed the applicant. The ASOs were allowed to be present during the discussion. The chair indicated that the case was taken over from the UK after 31 January 2020.

The eCA briefly introduced the dossier related to a biocidal product family containing hydrogen peroxide to be used as a surface disinfectant.

The discussion focussed on the items included in the open issues table. With regard to the first discussion point on the procedure followed for the efficacy follow up, the chair clarified that acceptance of additional data was considered justified taking into account the BPC document on “Introducing new information during the peer review process of an application for Union authorisation”. Some of the members did not agree with ECHA’s interpretation of the document and with the procedure that was followed for this case due to possible unequal treatment of applicants and the lack of peer review of the data submitted after the Working Group meeting. One member indicated that they would submit a minority opinion due to non-agreement with the procedure that was followed.

There were two open points remaining from the Working Groups, one related to efficacy and another one related to corrosiveness of metals.

The eCA introduced the issue regarding efficacy. Most of the members expressed that they would not consider the product to be efficacious, taking into account all data provided before the BPC. Therefore it was considered that efficacy was not demonstrated for this product family.

With regard to the corrosiveness to metals study the members agreed that the study is needed for the proper classification of the product.

The remaining open issues on the PAR and the BPC opinion were addressed. The chair indicated that the comments on the SPC would not be discussed due to the conclusion for this case.

The PAR and BPC opinion were adopted by majority, with one minority position due to the procedure followed for efficacy. The BPC concluded that the conditions of Article 19 of the BPR in terms of efficacy were not met. Therefore non-authorisation of the biocidal product family was proposed.

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 20 March 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.
- **Member (SE):** to submit the minority position by 12 March 2020.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by 1 April 2020.

9. Any Other Business

9.1 Follow up BPC e-consultation on open items forwarded by the ENV WG

Exceptions for groundwater assessment and extension of reference value scope

The BPC confirmed the proposed conclusions, e.g. that for inorganic rapidly reacting substances, carbon dioxide and substances included on Annex I of the BPR, no groundwater assessment is needed. .

With regard to the question if the reference value provided in Council Directive 2006/118/EC of 0.1 µg/L for groundwater can also be used for inorganic substances the BPC agreed in principle to the proposal in case no substance specific values are in place and provided that the toxicological reference values is not lower than 0.1 µg/L. COM confirmed that it it would be possible to use Council Directive 2006/118/EC although it is not mentioned in the BPR, as that Directive exists in any case and is applicable. It was agreed that COM and the SECR would consider this issue further[1].

[1] Comments provided by the member from SE received by the SECR after BPC-34 will be taken into account.

The BPC was further informed on the approach to harmonise the ground water assessment for inorganic substances initiated by DE (UBA) and on the conclusion of the AHEE that SECR will publish the related table prepared by DE on CIRCA.

RMM at product authorisation level for PT 8

The question raised is rather related to product authorisation and the CG may have more experience with regard to RMMs for wood preservative containing products. The item was therefore not further discussed at the BPC meeting and it was decided to forward this item to the CG.

Risk assessment of disinfection by-products

The aim of the discussion was to collect futher feedback of the BPC members but not to conclude, since the items is discussed already at CA meeting level and a parallel discussion should be prevented. It was re-confirmed that currently DBPs can only be assessed if sufficient guidance on relevant PTs is available. The BPC members also highlighted the importance of preparing further guidance on DBPs.

SE provided further feedback in writing to the above points after the BPC meeting, which will be taken into account in the reporting back to the ENV WG. The detailed feedback received during the BPC meeting on all above items will be collected in a separate document and shared with the ENV WG.

Actions:

- **SECR**: to prepare a document containing the detailed feeback provided at the BPC meeting and report it back to ENV WG.
- **SECR**: forward the item RMM at product authorisation level for PT 8 to the CG.

9.2 Revision of WG recommendation on in situ generated substances

ECHA is launching the Revising of the "In situ generated active substances – Risk assessment and implications on data requirements for active substances generated in situ and their precursors" (later on referred to as "WG recommendation"). The document "CA-July19-Doc.4.1-Final" establishes the principles for the management of product authorisation where the active substance is generated in situ. The document provides clarity on several aspects of product authorisation and triggers the need to amend the current WG recommendation.

A task group will be created from ECHA experts and volunteering WG members to work on the first re-draft. SECR asked the BPC members to encourage WG members having experience with in-situ generated active substances to participate to the task group.

Actions:

- **Members**: to investigate if they can nominate experts and inform SECR.

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

Agreed at the 34th meeting of BPC

4-5 March 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-33	
The revised version of the minutes of BPC-33 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 Programme for active substance approval **6.2 BPC Work Programme for Union authorisation**	
-	**Members:** to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by **13 March 2020.**
6.3 Outlook for BPC	
-	-
6.4 Status ED assessment for active substances	
-	**-**

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 chlorophene for PT 2	
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 **17 April 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 **24 March 2020** and publish it on the ECHA website.
7.3 Draft BPC opinion on glyoxal PT 2, 3 and 4	
The BPC adopted by majority 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 **17 April 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. **Member (SE):** to submit the minority position by **11 March 2020**. **SECR:** to forward the adopted opinion to COM by **24 March 2020** and publish it on the ECHA website.
7.4 Draft BPC opinion on Reaction mass of peracetic acid and peroxyoctanoic acid for PT 2, 3 and 4	
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 **17 April 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 **24 March 2020** and publish it on the ECHA website.
Item 8 – Union authorisation	
8.1 Update on Union authorisation	

8.2 Combining uses of different biocidal products in a BPF for exposure assessment	
The BPC took note of the document provided by the SECR.	**-**
8.3 Draft BPC opinions 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 **20 March 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 **1 April 2020**.
8.4 Draft BPC opinion on Union authorisation applications for a product family containing CMIT/MIT	
The BPC adopted by majority 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 **20 March 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. **Member (DE):** to submit the minority position by **12 March 2020**. **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by **1 April 2020**.
8.5 Draft BPC opinion on Union authorisation applications for a product family containing peracetic acid	
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 **20 March 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 **1 April 2020**. **Members**: to send their experience on similar cases (See comment 60 of the open issue table) to the COM by **26 March 2020**.

8.6 Draft BPC opinion on Union authorisation applications for a product family containing hydrogen peroxide	
The BPC adopted by majority 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 **20 March 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. **Member (SE):** to submit the minority position by **12 March 2020**. **SECR:** to forward the adopted opinion and final PAR to COM by **1 April 2020**.
Item 9 –Any other business	
9.1 Follow up BPC e-consultation on open items forwarded by the ENV WG	
The BPC discussed the document.	-
9.2 Revision of WG recommendation on in situ generated substances	
The BPC took note of the presentation.	**Members**: to investigate if they can nominate experts and inform SECR.

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Part III - List of Attendees

Members	European Commission
BALDASSARRI Lucilla (IT)	CHATELIN Ludovic (DG SANTE)
BRANDT Charlotte (BE)	CAINZOS GARCIA Marta (DG SANTE) *
BROVKINA Julija (LV)	GKINIS Georgios (DG SANTE) *
BUEHLER Dominique (CH)	NAGTZAAM Martinus (DG SANTE) *
CARBERRY Stephen (IE)	**Advisers**
CEBASEK Petra (SI)	BOITIER Caroline (FR) *
CHEZEAU Aurelie (FR) *	DUH Darja (SI) *
GONZALEZ MARQUEZ Maria Luisa (ES)	EHNI Markus (DE)
GREGERSEN Nina Falk (DK)	FRYDENLUND Jorid (NO)
HAHLBECK Edda (SE)	JARRETY Helene (BE)
HAKAITE Palmira (LT)	KIWAMOTO Reiko (NL) *
JAGER Stefanie (DE)	RIFFAUT Lea (FR) *
KOIVISTO Sanna (FI)	NIEMINEN Timo (FI)
LANS Martine (NL)	VUORENSOLA Katariina (FI)
MERISTE Anu (EE)	
MIKOLAS Jan (CZ)	**Invited experts**
RANDALL Marit (NO)	HUSZAL Sylwester (PL)
VAGIAS Vasileios (EL)	
VRHOVAC FILIPOVIC Ivana (HR)	**Accredited Stakeholder Observers**
	RITO Elias (FECC)
Alternate members	**ECHA Staff**
ENSCH Svenja (LU)	ESTEVAN MARTINEZ Carmen
SZENTGYORGYI Timea (HU)	JANKA Adel
	JARDIN Helene
	KURONEN Terhi
	PRIHA Outi
	SAEZ RIBAS Monica
	SCHIMMELPFENNIG Heike
	STASKO Jolanta
	VALKOVICOVA Eva
	VAN DE PLASSCHE Erik

	VAN GALEN Joost
Applicants	**Apologies**
BASF SE	AT
Contec Cleanroom (UK) Ltd Contec	CY
Ecolab Deutschland GmbH Ecolab	MT
Schuelke & Mayr GmbH	PT
Specialty Electronic Materials Switzerland GmbH	RO
	SK

(*) Remote participants

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-34

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-34 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2	BPC-A-34-2019_rev1	Draft agenda	
4	BPC-M-33-2019	Draft minutes from BPC-33	
5.2	-	Administrative issues and report from the other Committees	
6.1	BPC-34-2020-01	BPC Work Programme for active substance approval	
6.2	BPC-34-2020-02	BPC Work Programme for Union Authorisation	
6.3	BPC-34-2020-03	Outlook for the BPC	
6.4	BPC-34-2020-04	Status ED assessment for active substances	
7.1	Procedural and administrative aspects:		
	BPC-34-2020-05	7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval	
8.2	BPC-34-2020-13	Combining uses of different biocidal products in a BPF for exposure assessment	
9.1	BPC-34-2020-18	Follow up BPC e-consultation on open items forwarded by the ENV WG	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.2	BPC-33-2019-09A	Chlorophene PT 2	Draft BPC opinion
	BPC-33-2019-09B		Assessment report
	BPC-33-2019-09C		Open issues
7.3	BPC-34-2020-07A	Glyoxal PT 2	Draft BPC opinion
	BPC-34-2020-07B		Assessment report
	BPC-34-2020-07C		Open issues
	BPC-34-2020-08A	Glyoxal PT 3	Draft BPC opinion

	BPC-34-2020-07B		Assessment report
	BPC-34-2020-07C		Open issues
	BPC-34-2020-09A	Glyoxal PT 3	Draft BPC opinion
	BPC-34-2020-07B		Assessment report
	BPC-34-2020-07C		Open issues
7.4	BPC-34-2020-10A	Reaction mass of peracetic acid and peroxyoctanoic acid PT 2	Draft BPC opinion
	BPC-34-2020-10B		Assessment report
	BPC-34-2020-10C		Open issues
	BPC-34-2020-10D		HH WG Follow up document (for all PTs)
	BPC-34-2020-11A	Reaction mass of peracetic acid and peroxyoctanoic acid PT 3	Draft BPC opinion
	BPC-34-2020-10B		Assessment report
	BPC-34-2020-10C		Open issues
	BPC-34-2020-12A	Reaction mass of peracetic acid and peroxyoctanoic acid PT 4	Draft BPC opinion
	BPC-34-2020-10B		Assessment report
	BPC-34-2020-10C		Open issues
8.3	BPC-34-2020-14A	UA: product family containing propan-2-ol	Draft BPC opinion
	BPC-34-2020-14B		SPC
	BPC-34-2020-14C		PAR
	BPC-34-2020-14C1		Conf annex to PAR
	BPC-34-2020-14D		Open issues
8.4	BPC-34-2020-15A	UA: product family containing CMIT/MIT	Draft BPC opinion
	BPC-34-2020-15B		SPC
	BPC-34-2020-15C		PAR
	BPC-34-2020-15C1		Conf annex to PAR
	BPC-34-2020-15D		Open issues
8.5	BPC-34-2020-16A	UA: product family containing peracetic acid	Draft BPC opinion
	BPC-34-2020-16B		SPC
	BPC-34-2020-16C		PAR
	BPC-34-2020-16C1		Conf annex to PAR
	BPC-34-2020-16D		Open issues
8.6	BPC-34-2020-17A	UA: product family containing hydrogen peroxide	Draft BPC opinion
	BPC-34-2020-17B		SPC
	BPC-34-2020-17C		PAR
	BPC-34-2020-17C1		MS Conf annex to PAR
	BPC-34-2020-17D		Open issues

	BPC-34-2020-17E1		Additional doc on corrosion to metals: SI position paper
	BPC-34-2020-17E2		Additional doc on corrosion to metals
	BPC-34-2020-17E3		Additional doc on corrosion to metals
	BPC-34-2020-17E4		Additional doc on corrosion to metals
	BPC-34-2020-17E5		Additional doc on corrosion to metals
	BPC-34-2020-17F1		Additional doc on efficacy: SI position paper
	BPC-34-2020-17F2		Additional doc on efficacy:
	BPC-34-2020-17F3		Additional doc on efficacy:
	BPC-34-2020-17F4		Additional doc on efficacy:
	BPC-34-2020-17F5		Additional doc on efficacy:
	BPC-34-2020-19_Room doc 1		Overview: Efficacy studies

21 February 2020
BPC-A-34-2020_rev1

Draft agenda

34th meeting of the Biocidal Products Committee (BPC)

4 - 5 March 2020

ECHA Conference Centre, Telakkakatu 6, Helsinki

Starts on 4 March at 09:30, ends on 5 March at 18:00

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-34-2020

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-31

BPC-M-33-2019

For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

For information

6. – Work programme for BPC

6.1. BPC Work Programme for active substance approval

BPC-34-2020-01

For information

6.2. BPC Work Programme for Union authorisation

BPC-34-2020-02

For information

6.3. Outlook for BPC

BPC-34-2020-03

For information

6.4. Status ED assessment for active substances

BPC-34-2020-04

For information

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

7.1. Procedural and administrative aspects:

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

BPC-34-2020-05

For information

7.2. Draft BPC opinion on chlorophene for PT 2

Previous discussion: BPC-22

BPC-34-2020-06A, B, C

For adoption

7.3. Draft BPC opinion on glyoxal PT 2, 3 and 4

Previous discussion: WG–V-2019

PT 2: BPC-34-2020-07A, B, C
PT 3: BPC-34-2020-08A, C, BPC-34-2020-07B
PT 4: BPC-34-2020-09A, C, BPC-34-2020-07B

For adoption

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

7.4. Draft BPC opinion on Reaction mass of peracetic acid and peroxyoctanoic acid for PT 2, 3 and 4

Previous discussions: WG-III-2019, APCP WG-V-2019

PT 2: BPC-34-2020-10A, B, C
PT 3: BPC-34-2020-11A, C, BPC-34-2020-10B
PT 4: BPC-34-2020-12A, C, BPC-34-2020-10B

For adoption

8. – Union authorisation**

8.1 Update on Union authorisation

For information

8.2 Combining uses of different biocidal products in a BPF for exposure assessment

BPC-34-2020-13

For agreement

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

Previous discussion: WG-V-2019

BPC-34-2020-14A, B, C, D

For adoption

8.4 Draft BPC opinion on Union authorisation applications for a product family containing CMIT/MIT

Previous discussion: WG-V-2019

BPC-34-2020-15A, B, C, D

For adoption

8.5 Draft BPC opinion on Union authorisation applications for a product family containing peracetic acid

Previous discussion: WG-V-2019

BPC-34-2020-16A, B, C, D

For adoption

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

Previous discussion: WG-V-2019

BPC-34-2020-17A, B, C, D

For adoption

** For the discussions of the draft BPC opinions at least the following documents will be distributed: a draft BPC opinion (denoted by A), a draft 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. - Any other business

9.1 Follow up BPC e-consultation on open items forwarded by the ENV WG BPC-34-2020-18

For discussion

9.2 Revision of WG recommendation on in situ generated substances

For information

10. - Action points and conclusions

For agreement

Provisional time schedule for the

34th meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Telakkakatu 6, Helsinki

4 March 2020: starts at 09:30; 5 March 2020 ends at 18:00

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

Wednesday 4 March: morning session

Items 1-5	Opening items and administrative issues
Item 6	Work programme for BPC
	6.1. BPC Work Programme for active substance approval
	6.2. BPC Work Programme for Union authorisationl
	6.3. Outlook for BPC
	6.4. Status ED assessment for active substances
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 chlorophene for PT 2
Item 7.3	Draft BPC opinion on glyoxal PT 2, 3 and 4

Wednesday 4 March: afternoon session

Item 7.3	(cont'd)
Item 7.4.	Draft BPC opinion on Reaction mass of peracetic acid and peroxyoctanoic acid for PT 2, 3 and 4
Item 9.1	AOB: Follow up BPC e-consultation on open items forwarded by the ENV WG
Item 9.2	AOB: Revision of WG recommendation on *in situ* generated substances

Thursday 5 March: morning session

Item 8.1	Update on Union authorisation
Item 8.2	Combining uses of different biocidal products in a BPF for exposure assessment
Item 8.3	Draft BPC opinion on Union authorisation applications for a product family containing propan-2-ol
Item 8.4	Draft BPC opinion on Union authorisation applications for a product family containing CMIT/MIT
Item 8.6	Draft BPC opinion on Union authorisation applications for a product family containing hydrogen peroxide

Thursday 5 March: afternoon session

Item 8.6	(cont'd)
Item 8.5	Draft BPC opinion on Union authorisation applications for a product family containing peracetic acid
Item 9	AOB
Item 10	Action points and conclusions

End of meeting

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