10 December 2019

BPC-M-31-2019

Minutes of the 31st meeting of the Biocidal Products Committee (BPC)

25-26 June 2019

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chairman of the Biocidal Products Committee (BPC) welcomed the participants to the 31st BPC meeting.

Regarding the BPC membership, the Chairman stated that there are new appointed BPC members; Jan Mikolas from Czech Republic, Stephen Carberry from Ireland (official nomination pending), Lucilla Baldassarri from Italy (official nomination pending) and Dominique Buehler from Switzerland. The Chairman also stated that there are new appointed alternate BPC members; Anna-Maija Hämäläinen from Finland, Alessandro Ubaldi from Italy (official nomination pending), Kristine Krafte from Latvia, Horatiu Marcu from Romania, Ellen Schmalholz from Sweden and Lee Tipping from the United Kingdom.

The Chairman then informed the BPC members of the participation of 28 members, including 4 alternates. In addition, Belgium was represented by the advisor.

11 advisers and 3 representatives from accredited stakeholder organisations (ASOs) were present at the meeting. The representative from HEAL (Health & Environment Alliance), who was present for the first time, introduced the organisation to the meeting. A representative from the European Commission attended the meeting.

Applicants were invited and present for their specific substances under agenda item 7 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.

The Chairman stated that the UK is present and will also be invited to the BPC-32 meeting in October due to the developments on Brexit after the last BPC meeting. After the Brexit, which has been delayed to 31 October 2019, the UK is to be considered a third country and only following special agreements with the Executive Director of ECHA, with consent of the Commission, may UK representatives observe or participate in BPC meetings.

2. Agreement of the agenda

The Chairman introduced the final draft agenda (BPC-A-31-2019) and invited any additional items. With the addition of one item under AOB on 'Proposal from Germany on the assessment of the ED properties for the backlog substance Carbendazim' 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 destroyed 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-29

The revised draft minutes from BPC-29 (BPC-M-29-2018), incorporating the comments received, were agreed.

The Chairman noted that the actions from BPC-29 have been carried out.

The Chairman further informed the meeting on the following:

- The COM has been consulted on the application of Article 19(4) following the discussion on the draft opinion for the approval of metofluthrin for PT 19. The Chairman informed the meeting on the outcome of this consultation where the question was if an approval is possible based on a reference product which could not be authorised for the targeted users due to the provisions of Article 19(4) of the BPR. The COM concluded that approval is possible as Article 4(1) of the BPR, which sets the conditions for approval of active substances, does not refer to the conditions of Article 19(4). Those conditions are relevant for the biocidal product authorisation stage but not for the approval.
- The documents on the "Systematic literature review for ED assessment" (published on the BPC web-page under the "Working procedure for active substance approval") and "Biocides assessment and RAC opinion on harmonised classification" (published on the web-page of the Working Group – Human Health) were finalised. With respect to the latter the SECR will amend the working procedure on active substance approval by introducing that active substances with a classification for Muta Cat. 2 will require a RAC opinion before submission for peer review.
- The agreed revised working procedure for Union authorisation applications was revised and published on the BPC webpage.
- The document on post-authorisation conditions for Union authorisation was finalised and published on the BPC-webpage.
- No request was received from the member of BE to table a document for the BPC following the AOB on "External spraying devices for biocidal products" on BPC-29 agenda.
- The written consultation for the agreed silver draft opinions finished in the beginning of June. SECR will consult with SE on the next steps including the ED assessment.
- The next process flow for Union authorisation was published on the BPC webpage (process flow 34 with a WG in 11–22 November and the BPC 2-6 March 2020).
- For next year the number of BPC meetings will be reduced to four. Reasons for this decision is: i) the low number of draft opinions scheduled for both active substance approval and Union authorisation; ii) reducing the number of Working Group meetings. This means the documents containing the process flows for active substance approval and Union authorisation will be amended. The BPC welcomed this proposal.
- The Commission expressed concerns about the absence of delivery of BPC opinions on the Review Programme, and reminded BPC members that around 80 opinions have to be adopted to complete the Review Programme by the end of 2024.
- An e-consultation of the BPC members will be launched on several issue raised at the ENV WG with the aim to discuss these issues at the BPC in October.

Actions:

- **SECR:** to upload the agreed minutes from BPC-29 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.

5.2 Administrative updates and report from other ECHA bodies

The Chairman mentioned that the membership renewal exercise took place this spring and that the SECR has contacted those members from Member States whose official nomination is still missing.

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 13 draft opinions are scheduled for 2019 of which 10 are for the Review Programme. Of these 13 draft opinions, 1 has been adopted and 2 have been agreed (as the ED assessment is pending) at the previous meeting. The draft opinions scheduled for Cyanamid for PT 3 and 18 for the BPC in December are opinions which were returned to ECHA via an Article 75(1)(g) procedure by the Commission due to the ED assessment.
- For Union authorisation the number of scheduled opinions for 2019 is 12 of which 5 were adopted in the last BPC. The Chairman noted that this is a decrease from 24 estimated at the last BPC to 12. The Chairman refered to agenda item 8.1 for a further discussion.
- The COM and the SECR expressed their concerns with respect to the delays observed in the active substance and UA process.

The Chairman asked the eCAs with active substances and Union authorisations scheduled for discussion at the October 2019 BPC meeting (BPC-32) to confirm this planning to the SECR by 23 August 2019.

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 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 discussions at the Active Substance Workshop which took place on 12-13 February 2019, and called for more efficiency from Member States.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by **5 July 2019**.

6.4 Status harmonised classification and labelling for active substances

The SECR informed the meeting that the overview presented to the BPC members is the updated table concerning the CLH status of active substances which are approved under BPD/BPR or with adopted BPC opinions under BPR. This overview was presented at the CARACAL and CA meetings in March 2019. The update is based on the feedback from MSs after the meetings. The SECR asked the BPC members to provide further information on the status of CLH reports wich are requested for biocidal active substances and stated they will contact MSCAs on a bilateral basis concerning active substances for which a CLH dossier is missing.

Actions:

- **Members:** to provide comments on the overview by **30 August 2019**.

6.5 Status ED assessment for active substances

The SECR presented an overview on the status of the ED assessment of active substances. The overview shows the progress on ED assessments on active substances following BPC-29 and the actions planned by the eCAs including the proposed timelines as far as available. In total 47 active substance PT combinations for 21 active substances are on-hold due to the ED assessment.

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.

Actions:

- **Members:** to provide comments on the overview by **30 August 2019**.

6.6 Follow-up Active Substance Workshop 12-13 February 2019: Note ECHA on requesting additional information during the evaluation phase

The note was agreed by the members and will be revised subject to the comments made at the meeting.

Actions:

- **SECR:** to revise the document (including templates for letters) and publish it on BPC CIRCABC IG and make it available to stakeholders.

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 been changed compared to the previous versions with respect to the standard phrasing for PT 8. One member provide some futher comments on this phrase which was agreed.

Actions:

- **SECR:** to revise the document and publish it on BPC CIRCABC IG.

7.1.2 Confidentiality claims related to the address of the manufacturer(s) and location of the manufacturing site for the active substance

The members welcomed the document as this issue has occurred often during product authorisation. One member referred to a previous discussion at the CA meeting in which this was clarified in relation to Article 22(g): item 5.1.k of the 48th CA meeting of September 2012. One member stated that the practice under PPP is different. The representative of CEFIC referred to previous comments made by industry stating that no being able to claim this information as confidential may be in conflict with obligations for companies under other legislation. The Commission highlighted that hardly no information is confidential in an assessment report, as confidentiality is limited to very specific information as set out in the BPR. The meeting agreed with the proposal to harmonise the practice meaning that the address of the manufacturer(s) location of the manufacturing site for the active substance cannot be claimed confidential for active substance approval in the Assessment Report and for the SPC and PAR in product authorisation.

Related to this agenda item a member raised the question whether – due to the entry into force of new legislation on data protection – there is really a need to blacken the names of all study authors in the non-confidential (Product) Assessment Reports. The SECR will consult internally within ECHA on this question.

Actions:

- **SECR:** to revise the document and publish it on BPC CIRCABC IG.

7.2 Draft BPC opinion on DBNPA for PT 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 Chairman reminded that the substance had already been discussed at BPC-26 meeting but the opinion could not be adopted as at that time it did not contain an assessment of the ED properties. The eCA indicated that an ED assessment had been performed and disscussed at the ED EG meeting and the BPC Working Groups, where it had been concluded that DBNPA is an endocrine disruptor.

The BPC discussion focussed on whether a safe use can still be identified, considering that the substance is an ED. The BPC could not conclude on the acceptablility of the risk based on the ED properties of DBNPA and agreed to highlight the uncertainties concerning this assessment in the BPC opinion. It was indicated by the members that this is a general issue relevant for other active substances and required the SECR to initiate a discussion at Working Group level.

The applicant noted the discrepancies of the RAC opinion and the ED assessment in relation to effects on the thyroid. The RAC concluded that data are not sufficient to classify for thyroid effects whereas the ED EG came to the conclusion that the ED properties are based on thyroid effects. The SECR explained the different outcome with the different approaches used for data evaluation.

As the substance is considered an ED for human health and non-target organisms it meets the exclusion criteria and it is a candidate for substitution. The BPC therefore concluded that DBNPA should normally not be approved unless the conditions in Article 5(2) of the BPR are met.

It was noted that during the public consultation taking place during November 2018 – January 2019, no input from stakeholders had been received. The COM requested that the identification of potential alternatives to the use of DNBPA in PT4 is included in the BPC opinion. The SECR prepared an overview of already approved active substances for PT4, It was decided that the eCA will take this overview into consideration when finalising the BPC opinion.

The rest of the issues indicated in the open issues table were discussed and agreed by the Committee. The assessment report and BPC opinion 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 **9 August 2019**.
- **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 **11 July 2019** and publish it on the ECHA website.

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

7.3.1. PBO for PT 18

The member from EL informed the BPC about the evaluation of the data submitted after the approval. The BPC agreed with the evaluation of the data by EL.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **15 September 2019**.

7.4 Interpreting the definition of relevant impurities

The SECR presented the document, and its latest changes after a commenting round taking place before the BPC meeting. SECR will add the applicability date to the document and publish the adopted document, which was agreed without any further changes. One member expressed its concerns regarding the possibility that this document may lead to additional information requirements and stated that this would need to be monitored during the implementation phase of the document.

Actions:

- **SECR:** to revise the document and publish it on the BPC CIRCABC IG and 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) ongoing coordination activities by ECHA on coordination of the Union authorisation process.

The Commission expressed concerns on the delays in the processing of the applications for UA. In particular, some applications submitted in 2015 are still under evaluation, and some applications submitted in 2017 are still under the validation step.

SECR presented a new procedure for the linguistic check of the SPC translations, aimed at having the linguistic review of the SPCs only after the vote in the Standing Committee meeting. This procedure was welcomed by the BPC and was agreed to be applicable for the UA applications of this BPC-31 meeting. The procedure published on the BPC website will be updated accordingly.

Actions:

- **SECR:** to upload the presentation on the BPC CIRCABC IG.

8.2 Reporting the assessment of ED properties for the active substance and co-formulants in the BPC opinion

The SECR presented the proposal which was agreed by the BPC. The proposal was the following: in the BPC opinions there is a section "General" in the paragraph "3.2.1 BPC Conclusions of the evaluation; a) Summary of the evaluation and conclusions of the risk assessment". In this section the name of the active substance(s) and content in the biocidal product (family) is given. In addition, it is indicated if a substance of concern (SoC) is identified and if so the name of the substance is presented in the opinion as well as in the SPC. It is also included why the substance is considered to be a SoC: no detailed explanation but for example the classification is mentioned which led to the identification as a SoC. It is also indicated if no SoC has been identified. A more detailed description on the identification of SoC is presented in the (confidential) PAR. This approach will be applied also for reporting the results of the assessment of ED properties for the co-formulant or non-active substance.

Actions:

- **SECR:** to revise the document and publish it on the BPC CIRCABC IG.

8.3 Guidance on storage stability – Decision tree

The SECR introduced the document: the Coordination Group (CG) has received a number of referrals concerning the storage stability test and the associated shelf life, as Member States were applying different approaches. Hence, alignment was needed with regard to conclusions to be made considering the available information. The APCP Working Group discussed different cases on available data for deciding on the shelf life of biocidal products and agreed on the conclusion to be made for these different cases. Therefore the decision tree guarantees a consistent procedure within the Member States and it is expected to lead to a decrease in the number of referrals to the CG.

It was questioned by some members that the number of referrals will actually decrease as not all possible cases have been included in the decision tree. It was clarified by the SECR that the 10 cases addressed in the decision tree, are the major issues and referrals may not be avoidable for other issues which have to be addressed case-by-case. One member stated that the document is not in line with previous guidance on post authorisation data requirements adopted by the CG and BPC and asked for alignment. The SECR agreed to look into this. CEFIC complained that their comments have not been considered for this document. It was clarified by the SECR that the decision tree is a pure administrative and procedural document which does not considered any technical or scientific evaluation of stability studies. Therefore, CEFIC was not expected to comment on this document. Nevertheless, SECR invited CEFIC to provide their comments for distribution.

The BPC members agreed on the decision tree.

Actions:

- **SECR:** to revise the document and publish it on the BPC CIRCABC IG and inform the CG.

8.4 Draft BPC opinions on Union authorisation applications for a product family containing octanoic acid

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 draft PAR, SPC and the draft BPC opinion.

All 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, the PAR and the draft SPC 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 **5 July 2019**.
- **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 **11 July 2019**.

8.5 Draft BPC opinions on Union authorisation applications for a product family containing octanoic acid and decanoic acid

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 received on the draft PAR, SPC and the draft BPC opinion.

A considerable number of the open issues was related to editorial changes (e.g., information alignment in the draft documents) and changes agreed during the WGs which were not fully implemented in the updated documents. Several open points were addressed with the amended draft PAR and the draft BPC opinion provided directly before the meetings. The SECR proposed to close those points in the open issue table.

Discussion took place for other open points:

- The Chair informed the applicant that active substance manufacturer data cannot be considered as confidential information in accordance with the provisions of the BPR. Therefore, the PAR should not be amended.
- The BPC members discussed the conditions for storage implemented for the products in the metaSPC1. Considering the submitted data it was clarified that the following restriction for product storage “The biocidal product must not be stored at temperature higher than 30ºC.” should be applied.

- Taking into account the composition of the products and the pH restriction discussion at the Efficacy WG, the BPC members requested to include the sentence "*In order to guarantee efficacy of future products in metaSPC1, any new products must contain sufficient amounts of acids to yield a pH≤ 2 at the use dilution of 1.5 %.*" in Section 2.1. of SPC. This restriction is related to possible future product notifications within the product family. However, considering technical limitations of the SPC Editor, it was agreed that this sentence will be included in Section 6 of the metaSPC1.
- The BPC members discussed several risk management measures (RMMs). The members agreed on the RMMs to be included in the relevant sections of the draft SPC.
- A number of comments were related to the qualitative and quantitative information on the composition of the products. This information was clarified by the eCA.
- With regards to the BPC opinion a member asked to harmonise sentences related to the BPR articles though all UA opinions as well as to simplify the level of details provided in relation to the physical chemical properties and efficacy assessment.

Taking into account the CA document (CA-May15-Doc.4.6a) the Commission asked to include the term "non-active substance" in the function field of the co-formulants included in the SPC.

In addition the Commission asked clarification whether the precautionary statement P234+P390 should be applied since the product is classified as "May be corrosive to metals", as it had been applied for two previous cases where the products are classified as "May be corrosive to metals". This point was clarified by the eCA, indicating that those precautionary statements are not applicable in this particular case.

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

The BPC opinion, the PAR and the draft SPC 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 **5 July 2019**.
- **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 **11 July 2019**.

8.6 Draft BPC opinions on Union authorisation applications for a product family containing permethrin and S-methoprene

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 received on the draft PAR, SPC and the draft BPC opinion.

The Chairman informed that in addition to the open issues table a room document containing information from the UK Veterinary Medicines Directorate related to the sensitivity of cats to permethrin was made available by the SECR. This information was received after the SECR contacted EMA on the situation under their legislation for veterinary medicines containing permethrin.

Some editorial mistakes were noticed by the applicant including the company name. The BPC agreed to amend the draft PAR, draft SPC and the draft BPC opinion without further discussion. The same applied to several other open issues where the BPC agreed to amend the draft PAR, draft SPC and the BPC opinion.

The main focus of the discussion was to ensure that adequate risk mitigation measures (RMMs) are introduced due to the permethrin toxicity for cats. Due to lack of guidance the eCA performed a quantitative risk assessment (RA) for dogs based on a non-harmonised methodology. According to the eCA the parameters used for this risk assessment represent a worst case. For cats it was not possible to perform a quantitative risk assessment as not threshold can be derived for cats. Therefore a qualitative assessment was performed by minimising exposure as much as possible. The eCA considered the proposed RMMs as adequate to limit the exposure for cats such that risk are acceptable.

ECHA presented the room document and informed that in addition the DE CA for veterinary medicinal products was contacted by the SECR. Most incidents with cats occur, when spot-on products for dogs (which contain a high concentration of permethrin) are applied on cats. At the same time there are authorised products on the EU market containing permethrin (low concentration), like shampoos, sprays and powders which can be safely applied on cats.

In general it was underlined that in cases where it is very difficult or impossible to perform a risk assessment for pets, appropriate and restrictive RMMs should apply. Several members considered the proposed RMMs for this biocidal product intended to be used by the general public as unrealistic and maybe not adequate: i) it is difficult to avoid exposure by closing the room(s) where treatment has taken place noting the product is efficacious up to 6 months; ii) it is difficult if not impossible to keep cats away from treated objects; iii) the product cannot be compared to the veterinary medicinal product as here the exposure is via contact with a treated surface (carpets or furniture) for a prolonged period of many months. The eCA informed that under national authorisation similar products have already been authorised and stated – supported by some other members - that according to them the introduced RMMs are sufficient to enable the authorisation of the product. It was also mentioned that the incidences in the UK – as shown in the room document - of cat poisoning are relatively low either based on the number of “dog spot-on doses sold” or based on the doses sold for other products like powders, sprays and shampoos.

The applicant stated that with reference to primary exposure cats are not continuously in contact with the product applied on the surfaces, so the potential risk is under control.

With reference to secondary exposure, the proposed RMMs limit the contamination of animals by the dried product.

Finally the BPC agreed to amend the proposed RMM 'Avoid prolonged contact of pets, particularly cats, to treated surfaces' with 'Keep cats away from treated surfaces due to high sensitivity to permethrin toxicity' . In addition, the use of the product for pet baskets will be removed.

Another discussion took place in relation to the proposed risk mitigation measure for the environment and if the members consider them as relastic for the applied uses. The eCA explained that a minimum release to the environment via punctual and targeted cleaning of non-washable furnitures and home textiles (no washing and not wet cleaned) was considered in the risk assessment which did not result in an unacceptable risk. The measures are proposed to limit as far as possible this punctual/targeted cleaning. The members agreed with the RMMs proposed by the eCA.

All items in the open issues table were addressed. The BPC opinion, the draft SPC and the draft 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 BPC member (SE) filed a minority opinion and one member (FI) abstained.

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 **5 July 2019**.
- **Member (SE):** to submit the minority opinion to the SECR by **4 July 2019**.
- **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 **11 July 2019**.

9. Any Other Business

9.1 Consultation Forum sub-group on BPR (BPRS) on risk management measures

The SECR presented the document and explained that the BPRS will be consulted for advising on the enforceability of RMMs used in section 2.4 of at present adopted and published BPC opinions. One member noted that in future also in section 2.3 of the opinions RMMs might occur. The SECR pointed out that ad hoc advise from the BPRS would be possible if needed. It was also proposed to consider the harmonised phrases from the SPCs and RMMs in UA opinions for further BPRS consultation. Additionally, the implication if RMMs are not enforceable was questioned as well as the status of advise of BPRS versus BPC. The SECR pointed out that BPRS consultation should be considered as rather an informal advice. The proposal to consult BPRS on all in the document listed RMMs was supported by the BPC.

Actions:

- **SECR:** to revise the document and publish it on the BPC CIRCABC IG.
- **SECR:** to forward the document to the BPRS Secretariat initiating the consultation.

9.2 Risk assessment of the professional user – combination of exposure from product use and dietary intake

One BPC member presented a document on risk assessment of the professional user including non-biocidal use in the exposure asssement, referring mainly to substances with significant dietary exposure. The document was discussed in the meeting and members pointed out that lack of guidance should not be used as an argument to exclude the assessment of aggregated exposure of professionals. Some members argued that the biocidal use should not be restricted due to aggregated exposure to substances which are used in high amount under other regulations. The COM pointed out that the approach for assessing the combination of exposure from product use and dietary intake for iodine containing products should not differ between professional users and other exposed groups. The BPC member who presented the document also argued that this approach is currently not used for environmental risk assessment. As example, for pyrethroids the combination of the emissions from use in biocidal products and plant protection products is not assessed, although these active substances are well-known for their toxicity to bees. It was also pointed out that a high level of human health protection is required under BPR. No final agreement could be reached in the BPC. It was decided to ask the BPC for comments via a written procedure after which the SECR and the member involved will discuss the way forward on how to proceed with the issues raised.

Actions:

- **SECR:** to open a Newsgroup for commenting on the proposal by **30 August 2019**.

9.3 Proposal from Germany on the assessment of the ED properties for the backlog substance Carbendazim

The proposal from the member from DE was discussed.

Actions:

- **SECR:** to open a Newsgroup for commenting on the proposal by **30 August 2019**.

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 31st meeting of BPC

25-26 June 2019

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-29	
The revised version of the minutes of BPC-29 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 2018-2019 for active substance approval **6.2 BPC Work Programme 2018-2019 for Union authorisation**	
-	**Members:** to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by **5 July 2019.**
6.3 Outlook for BPC	
-	-
6.4 Status harmonised classification and labelling for active substances	
-	**Members:** to provide comments on the overview by **30 August 2019**
6.5. Status ED assessment for active substances	
-	**Members:** to provide comments on the overview by **30 August 2019**
6.6. Follow-up Active Substance Workshop 12-13 February 2019: Note ECHA on requesting additional information during the evaluation phase	

The BPC discussed the proposal.	**SECR:** to revise the document (including templates for letters) and publish it on BPC CIRCABC IG and make it available to stakeholders.
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.	-
7.1.2 Confidentiality claims related to the address of the manufacturer(s) and location of the manufacturing site for the active substance	
The BPC agreed on the proposal.	**SECR**: to revise the document and publish it on BPC CIRCABC IG.
7.2 Draft BPC opinion on DBNPA for PT 4	
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 **9 August 2019.** **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 **11 July 2019** and publish it on the ECHA website.
7.3 Revised Assessment Report following the submission of data after active substance approval	
7.3.1 PBO for PT 18	
The member from EL informed the BPC about the evaluation of the data submitted after the approval. The BPC agreed with the evaluation of the data by EL.	
7.4 Interpreting the definition of relevant impurities	
The BPC agreed on the document.	**SECR:** to revise the document and publish it on the BPC CIRCABC IG and the ECHA website.
Item 8 – Union authorisation	
8.1 Update on Union authorisation	
The meeting was informed about the developments on Union authorisation.	**SECR:** to upload the presentation on the BPC CIRCABC IG.
8.2 Reporting the assessment of ED properties for the active substance and co-formulants in the BPC opinion	
The BPC agreed on the proposal.	**SECR:** to revise the document and publish it on the BPC CIRCABC IG.

8.3 Guidance on storage stability – Decision tree	
The BPC agreed on the proposal.	**SECR:** to revise the document and publish it on the BPC CIRCABC IG and inform the CG.
8.4 Draft BPC opinion on Union authorisation applications for a product family containing octanoic 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 **5 July 2019**. **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 **11 July 2019**.
8.5 Draft BPC opinion on Union authorisation applications for a product family containing octanoic acid and decanoic 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 **5 July 2019**. **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 **11 July 2019**.
8.6 Draft BPC opinion on Union authorisation applications for a product family containing permethrin and S-methoprene	
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 **5 July 2019**. **Member (SE):** to submit the minority opinion to the SECR by **4 July 2019**. **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 **11 July 2019**.
Item 9 –Any other business	
9.1 Consultation Forum sub-group on BPR (BPRS) on risk management measures	

The BPC discussed the document.	**SECR:** i) to revise the document and publish it on the BPC CIRCABC IG; ii) to forward the document to the BPRS Secretariat initiating the consultation.
9.2 Risk assessment of the professional user – combination of exposure from product use and dietary intake	
The BPC discussed the document.	**SECR:** to open a Newsgroup for commenting on the proposal by **30 August 2019**.
9.3 Proposal Germany on the assessment of the ED properties for the backlog substance Carbendazim	
The BPC discussed the document.	**SECR:** to open a Newsgroup for commenting on the proposal by **30 August 2019**.

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Part III - List of Attendees

Members	European Commission
BALDASSARRI Lucilla (IT)	CHATELIN Ludovic (DG SANTE)
BORGES Teresa (PT)	GKINIS Georgios (DG SANTE)
BROVKINA Julija (LV)	
CARBERRY Stephen (IE)	**Advisers**
CHÉZEAU Aurélie (FR)	COUGNON Thomas (BE)
CEBASEK Petra	JARRETY Hélène (BE)
COSTIGAN Michael (UK)	LEPAGE Anne (BE)
DRAGOIU Simona (RO)	EHNI Markus (DE)
GAVRIEL Alexandros (CY)	KRAUS Sabrina (DE)
GONZALEZ MARQUEZ Maria Luisa (ES)	WEINHEIMER Viola (DE)
GREGERSEN Nina Falk (DK)	JENSEN Stine (DK)
HADAM Anna (PL)	KOIVISTO Sanna (FI)
HAHLBECK Edda (SE)	RAT Benjamin (FR)
HAKAITE Palmira (LT)	VISSER Alette (NL)
JAGER Stefanie (DE)	TORGERSEN Trine-Lise (NO)
JOHN Nina (AT)	
LANS Martine (NL)	**Accredited Stakeholder Observers**
MERISTE Anu (EE)	CINGOTTI Natacha (HEAL)
MIKOLAS Jan (CZ)	DREVE Simina (FECC)
MIKOLASKOVA Denisa (SK)	MIHAI Camelia (CEFIC)
RANDALL Marit (NO)	
VAGIAS Vasileios (EL)	**ECHA Staff**
VRHOVAC FILIPOVIC Ivana (HR)	AIRAKSINEN Antero
ZIGRAND Jeff (LU)	ESTEVAN MARTINEZ Carmen
Alternate members	KREBS Bernhard
HAMALAINEN Anna-Maija (FI)	KURONEN Terhi
MALLIA Lothar Paul (MT)	MULLER Gesine
PYTHON François (CH)	MYOHANEN Kirsi
SZENTGYORGYI Timea (HU)	RUGGERI Laura
	STASKO Jolanta
	SZYMANKIEWICZ Katarzyna

	VAN DE PLASSCHE Erik
Applicants	**Apologies**
Agrobiothers	
Endura S.p.A.	
HYPRED SA	
SOPURA	
Specialty Electronic Materials Switzerland GmbH	

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-31

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-31 meeting

Meeting documents		
Agenda Point	**Number**	**Title**
2	BPC-A-31-2018_rev1	Draft agenda
4	BPC-M-29-2018	Draft minutes from BPC-29
5.2	-	Administrative issues and report from the other Committees
6.1	BPC-31-2019-01	BPC Work Programme for active substance approval
6.2	BPC-31-2018-02	BPC Work Programme for Union Authorisation
6.3	BPC-31-2018-03	Outlook for the BPC
6.4	BPC-31-2019-04	Status harmonised classification and labelling for active substances
6.5	BPC-31-2019-05	Status ED assessment for active substances
6.6	BPC-31-2019-09	Follow-up Active Substance Workshop 12-13 February 2019: Note ECHA on requesting additional information during the evaluation phase
7.1	Procedural and administrative aspects:	
	BPC-31-2019-06	7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval
	BPC-31-2019-07	7.1.2. Confidentiality claims related to the address of the manufacturer(s) and location of the manufacturing site for the active substance
7.3	Revised Assessment Report following the submission of data after active substance approval:	
	BPC-31-2019-10	7.3.1. PBO for PT 18
7.4	BPC-31-2019-11	Interpreting the definition of relevant impurities
8.2	BPC-31-2019-12	Reporting the assessment of ED properties for the active substance and co-formulants in the BPC opinion
8.3	BPC-31-2019-13	Guidance on storage stability – Decision tree
9.1	BPC-31-2019-17	Consultation Forum sub-group on BPR (BPRS) on risk management measures

9.2	BPC-31-2019-18	Risk assessment of the professional user – combination of exposure from product use and dietary intake	
9.3	BPC-31-2019_20_Room doc 2	Room doc 2: DE letter on Carbendazim	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.2	BPC-31-2019-08A	DBNPA - PT 4	Draft BPC opinion
	BPC-31-2019-08B		Assessment report
	BPC-31-2019-08C		Open issues
	BPC-31-2019_21_Room doc 3		Room doc 3: Identification of potential alternatives to DBNPA
8.2	BPC-31-2019-14A	UA: product family containing octanoic acid	Draft BPC opinion
	BPC-31-2019-14B		SPC
	BPC-31-2019-14C		PAR
	BPC-31-2019-14C1		Conf annex to PAR
	BPC-31-2019-14D		Open issues
	BPC-31-2019-15A	UA: product family containing octanoic acid and decanoic acid	Draft BPC opinion
	BPC-31-2019-15B		SPC
	BPC-31-2019-15C		PAR
	BPC-31-2019-15C1		Conf annex to PAR
	BPC-31-2019-15D		Open issues
8.3	BPC-31-2019-16A	UA: product family containing permethrin and S-methoprene	Draft BPC opinion
	BPC-31-2019-16B		SPC
	BPC-31-2019-16C		PAR
	BPC-31-2019-16C1		Conf annex to PAR
	BPC-31-2019-16D		Open issues
	BPC-31-2019-19_Room doc 1		Room doc 1: Permethrin: “Don’t put your cat at risk” (Veterinary Medicines Directorate)

13 June 2019
BPC-A-31-2019_rev1

Draft agenda

31st meeting of the Biocidal Products Committee (BPC)

25 - 26 June 2019

ECHA Conference Centre, Annankatu 18, Helsinki

Starts on 25 June at 09:30, ends on 26 June at 18:00

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-31-2019_rev1

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-29

BPC-M-29-2019

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-31-2019-01

For information

6.2. BPC Work Programme for Union authorisation

BPC-31-2019-02

For information

6.3. Outlook for BPC

BPC-31-2019-03

For information

6.4. Status harmonised classification and labelling for active substances

BPC-31-2019-04

For information

6.5. Status ED assessment for active substances

BPC-31-2019-05

For information

6.6. Follow-up Active Substance Workshop 12-13 February 2019: Note ECHA on requesting additional information during the evaluation phase

BPC-31-2019-09

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-31-2019-06

For information

7.1.2. Confidentiality claims related to the address of the manufacturer(s) and location of the manufacturing site for the active substance

BPC-31-2019-07

For agreement

7.2. Draft BPC opinion on DBNPA for PT 4

Previous discussion: BPC-26

BPC-31-2019-08A, B, C

For adoption

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

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

7.3.1. PBO for PT 18

BPC-31-2019-10
For agreement

7.4. Interpreting the definition of relevant impurities

BPC-31-2019-11
For agreement

8. – Union authorisation**

8.1 Update on Union authorisation

For information

8.2 Reporting the assessment of ED properties for the active substance and co-formulants in the BPC opinion

BPC-31-2019-12
For agreement

8.3 Guidance on storage stability – Decision tree

BPC-31-2019-13
For agreement

8.4 Draft BPC opinions on Union authorisation applications for a product family containing octanoic acid

Previous discussion: WG-II-2019

BPC-31-2019-14A, B, C, D
For adoption

8.5 Draft BPC opinions on Union authorisation applications for a product family containing octanoic acid and decanoic acid

Previous discussion: WG-II-2019

BPC-31-2019-15A, B, C, D
For adoption

8.6 Draft BPC opinions on Union authorisation applications for a product family containing permethrin and S-methoprene

Previous discussion: WG-II-2019

BPC-31-2019-16A, 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 Consultation Forum sub-group on BPR (BPRS) on risk management measures

BPC-31-2019-17

For discussion

9.2 Risk assessment of the professional user – combination of exposure from product use and dietary intake

BPC-31-2019-18

For discussion

10. - Action points and conclusions

For agreement

Provisional time schedule for the

31st meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Annankatu 18, Helsinki

25 June 2019: starts at 09:30; 26 June 2019 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.

Tuesday 25 June: morning session

Items 1-5	Opening items and administrative issues	
Item 6	Work programme of the 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 harmonised classification and labelling for active substances
	6.5.	Status ED assessment for active substances
	6.6	Follow-up Active Substance Workshop 12-13 February 2019: Note ECHA on requesting additional information during the evaluation phase
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
	7.1.2.	Confidentiality claims related to the address of the manufacturer(s) and location of the manufacturing site for the active substance
Item 7.2	Draft BPC opinion on DBNPA for PT 4	

Tuesday 25 June: afternoon session

Item 7.3.	Revised Assessment Report following the submission of data after active substance approval:	
	7.3.1	PBO for PT 18
Item 7.4.	Interpreting the definition of relevant impurities	
Item 9.1	Consultation Forum sub-group on BPR (BPRS) on risk management measures	
Item 9.2	Risk assessment of the professional user – combination of exposure from product use and dietary intake	

Wednesday 26 June: morning session

Item 8.1	Update on Union authorisation
Item 8.2	Reporting the assessment of ED properties for the active substance and co-formulants in the BPC opinion
Item 8.3	Guidance on storage stability – Decision tree
Item 8.4	Draft BPC opinions on Union authorisation applications for a product family containing octanoic acid

Wednesday 26 June: afternoon session

Item 8.5	Draft BPC opinions on Union authorisation applications for a product family containing octanoic acid and decanoic acid
Item 8.6	Draft BPC opinions on Union authorisation applications for a product family containing permethrin and S-methoprene
Item 10	Action points and conclusions

End of meeting

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