25 June 2019

BPC-M-29-2019

Minutes of the 29th meeting of the Biocidal Products Committee (BPC)

26 February – 1 March 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 29th BPC meeting.

Regarding the BPC membership, the Chairman stated that there is a new alternate BPC member for Denmark, Birgitte Skou Cordua. The Chairman also stated that there are new appointments from Lithuania: Palmira Hakaite is a new BPC member and Saulius Majus a new alternate BPC member.

The Chairman then informed the BPC members of the participation of 28 members, including 6 alternates.

8 advisers and 2 representatives from accredited stakeholder organisations (ASOs) were present at the meeting. The representative from FECC (European Association of Chemical Distributors), 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 (except for carbendazim where the applicant was not present) 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 will not participate in the BPC meetings anymore after 30 March 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-29-2019) and invited any additional items. With the addition of one items under AOB on ‘external spraying devices’ 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-28

The revised draft minutes from BPC-28 (BPC-M-28-2018), incorporating the comments received, were agreed.

The Chairman noted that the actions from BPC-28 have been carried out.

The Chairman further informed the meeting: i) that the written consultation for the agreed silver draft opinions will be postponed to the beginning of March; ii) concerning the clarifications given by the Commission in relation to the use of human data for an active substance approval case; iii) the agreement of the Coordination Group on the applicability of TAB entries as this document will also apply to Union authorisation.

Actions:

- **SECR:** to upload the agreed minutes from BPC-28 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 request to renew the BPC membership has been sent to the EU Permanent Representations of those MS's whose BPC membership will expire this spring, and that ECHA expects to get the information on renewals or new appointments from those MS's by 31 March 2019.

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

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 15 draft opinions are scheduled for 2019 of which 9 are for the Review Programme;
- For Union authorisation the number of scheduled opinions for 2019 is 17. The Chairman refered to agenda item 8.1 for a further discussion.

The Chairman asked the eCAs with active substances scheduled for discussion at the June 2019 BPC meeting (BPC-31) to confirm this planning to the SECR by 13 May 2019.

SECR informed the meeting of the major findings of the Active Substance Workshop which took place on 12-13 February 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 meetings to BPC meetings. Progress must also be made on backlog reports submitted before 1st September 2013. The Commission referred also to the discussions of 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 **8 March 2019**.
- **SECR**: on the basis of the changes to update the Work Programme for active substance approval on the ECHA website and in the BPC CIRCABC IG.
- **The relevant eCAs** to confirm to the SECR that their active substances scheduled for discussion at June BPC meeting will remain on track by **13 May 2019**.

6.4 Status harmonised classification and labelling for active substances

The SECR informed the meeting that there have been no changes in the overview on the status of harmonised classification and labelling of active substances since BPC-28. The SECR further informed the meeting that ECHA has drafted a document concerning the CLH status based on this overview for CARACAL and the Biocides CA meeting in March 2019 requesting the involved Member States to take action for their substance(s).

The Commission also indicated that it took note of the issues expressed by some Member States during the Active Substance Workshop, and indicated that some discussions will take place between Commission and ECHA to ensure that the BPR constraints are better taken into account by the CLP area.

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-28 and the actions planned by the eCAs including the proposed timelines as far as available. In total 45 active substance PT combinations 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 is monitored and reported.

Actions:

- **Members:** to provide comments on the overview by **8 March 2019**.

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 has not been changed compared to the previous versions. It is listed for information and members preparing BPC opinions are asked to make use of the standard phrases.

7.2 Draft BPC opinion on epsilon-metofluthrin for PT 19

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 AR and the draft BPC opinion.

The eCA informed that due to a change in the manufacturing source the active substance can now be considered as a mono-consitutuent substance and the name epsilon-metofluthrin is now applicable.

The Committee discussed the need to revise the groundwater assessment to take into account the harmonised list of endpoints for the pyrethroids metabolites in regards to degradation and persistence of metofluthrin metabolites. The SECR informed about the status of the harmonisation and the BPC members considered it necessary to update the groundwater assessment before agreeing on the assessment. Therfore, the eCA will bring a revised assessment for peer-review.

The BPC also noted that, based on the classification of the representative biocidal products as Acute Tox 3 and STOT SE1, these products cannot be authorised for use by the general public in accordance with Article 19(4)(b) of the BPR. Since the representative products are supported only for use by non-professionals, the SECR and the Commisssion will further discuss on how to address this element and whether an approval would still be possible or not as Article 4(1) of the BPR, listing the conditions for approval, does not make reference to Article 19(4)(b).

The Commission asked to the applicant whether it would be possible to develop biocidal products for the general public which would not have these hazardous classifications. The applicant replied expressing its disagreement on the RAC conclusions on the harmonised classification of the active substance.

The eCA and SECR noted that since the assessment of endocrine-disrupting properties has not yet been finalised, it will need to be peer-reviewed before the adoption of the BPC opinion.

Due to the UK withdrawal the new eCA in charge of finalising the assessment for this active substance will be Spain.

The rest of the issues indicated in the open issues table were discussed and agreed by the Committee.

Actions:

- **SECR:** to consult with the Commission on the application of Article 19(4)(b) in relation to the approval of the active substance.
- **Rapporteur:** to perform the groundwater risk assessment and ED assessment and return the opinion and Assessment Report to ECHA.

7.3 Draft BPC opinion on azametiphos for PT 18

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 AR and the draft BPC opinion.

The conclusion on the P criteria was discussed by the Committee. The eCAeCA clarified that they had not yet updated the PBT assessment following the technical discussion at the Environment Working Group III of 2016. They proposed to revise the section by summarising all available information and use weight of evidence approach (WoE) to draw a conclusion on the P criterion. The step-wise assessment will also include the PBT assessment of the metabolites and it will be peer-reviewed before the BPC. The applicant informed the meeting that a QSAR analysis and additional analytical data on hydrolysis was submitted to the eCA to support the assessment. Additionally, the applicant explained that they are planning new studies to identify the metabolites and highlighted the technical difficulties to perform the photolysis study. The Chairman concluded that at this point in time no additional information is needed and the QSAR analysis will be used within the WoE analysis.

The Commission asked whether the ready-to-use products referred in the draft opinion were already present on the market, as the safe use is only shown for these products. The applicant answered that it intends to develop such products in the future.

The eCA and SECR noted that since the assessment of endocrine-disrupting properties has not yet been finalised, it will need to be peer-reviewed before the adoption of the BPC opinion.

Due to the UK withdrawal the new eCA in charge of finalising the assessment for this active substance will be Italy.

The Commission remarked that it is indicated in section 2.5 of the draft opinion that some data are still missing after 10 years of examination, reminded that all data should normally be provided at the submission of applications, and strongly invited the applicant to provide the missing data before the BPC opinion is finalised as the ED assessment is still on-going.

The rest of the issues indicated in the open issues table were discussed and agreed by the Committee.

Actions:

- **Rapporteur:** to perform the PBT and ED assessment and return the opinion and Assessment Report to ECHA.

7.4 Draft BPC opinion on carbendazim for PT 9

The Chairman stated that ASOs were allowed to be present during the discussion. The applicant was invited to attend to the meeting, and was not present. The discussion focussed on the items included in the open issues table regarding the comments on the AR and the draft BPC opinion.

The eCA presented the non-approval proposal. The issues indicated in the open issues table were discussed and agreed by the Committee. The draft opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **12 April 2019.**
- **SECR:** to revise the draft opinions 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 **19 March 2019** and publish it on the ECHA website.

7.5 Revised Assessment Report following the submission of data after active substance approval

7.5.1. Peracetic acid generated from TAED and sodium percarbonate for PT 2, 3 and 4

The eCA informed the meeting that the review programme participants of the active substance provided the additional information requested in the BPC opinion by the set deadline. The BPC agreed on the evaluation performed by the eCA.

Actions:

- **Member (FI):** to forward the revised assessment report with the List of Endpoints and the updated reference specification to the SECR by **19 April 2019**.

7.6 Systematic literature review for ED assessment

The document concerns those active substances for which the CAR was submitted before 1 September 2013. SECR informed that the document was amended with respect to the version discussed at the previous BPC meeting mainly for the following aspects:

- Where the applicant does not provide a systematic literature review, the eCA would perform a literature review that could initially be less extensive than a systematic literature review according to the ED criteria and guidance.
- The eCA would perform a systematic literature review according to the ED criteria and guidance if the likely result of the assessment is that the substance should be considered to have ED properties.

The members agreed with the principles and the document was adopted with minor amendments.

Actions:

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

7.7 Biocides assessment and RAC opinion on harmonised classification (CLH)

The document clarifies the interdependence of the biocides process and the RAC process for CLH. Following the previous discussion at BPC-28 the document was amended mainly by clarifying the language and explaining the background with respect to mutagenicity. In addition, it was proposed that a RAC opinion would be required for substances for which the eCA is proposing Muta. 2 classification, because the consequences of this classification for the risk assessment can be severe. The document was agreed with minor text changes. The working procedure will be amended to include in the accordance check a requirement of a RAC opinion if Muta. 2 is proposed.

Actions:

- **SECR:** to revise the document and publish it on BPC CIRCABC IG.
- **SECR**: to amend working procedure for active substance approval.

7.8 Interpreting the definition of relevant impurities

The SECR presented the document, its latest changes and the history of the development of the document. SECR clarified the urgent need to have a harmonised way for assessing which impurities are relevant and stated it did not foresee more work to the eCAs due to this document. SECR provided replies to all the comments provided during the commenting period. One member had provided extensive comments during written commenting, and a bilateral discussion with SECR took place before the discussion of this agenda item in order to clarify most of the the concerns of that member. As an outcome of that discussion, the scope of the document will be clarified in more detail also explaining what issues are not covered by this document. SECR furthermore explained that this document can be amended in future if it turns out that it does not work in practise. Some issues for future guidance development regarding renewals were identified. Two members were considering that the commenting period was too short and more time should be given for commenting on the document. For commenting, SECR proposed to not focus on technical issues which have been already discussed in Working Groups, but rather on additional issues not included in the document which may need further guidance.

Actions:

- **SECR:** to open a Newsgroup for commenting on the proposal by **29 March 2019** and prepare a revised document for the next BPC meeting**.**

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 applications in ECHA's pipeline; ii) an overview of the applications received since the last BPC; iii) an update concerning the UA-BBPs where ECHA will start requesting a list of existing national product authorisations; and iv) a reminder concerning the update of PAR, draft SPC and potentially the IUCLID file following the WG and BPC discussions .

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. The Commission invited the responsible eCA(s) to conclude on these dossiers, or reject them if they are incomplete.

Actions:

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

8.2 Draft BPC opinion on Union authorisation application for a product family containing iodine / PVP-iodine

8.2.1 Draft BPC opinion on Union Authorisation application for a product family containing iodine

The Chairman welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The discussion focussed on the items included in the open issues table.

With reference to the new use introduced for this product family it was agreed to add as a risk mitigation measure for the possibility of combined use for stable disinfection and teat disinfection by the same person: "Only use one kind of Iodine-containing product per day".

Furthermore for professionals, carrying out only stable disinfection it will be added that they must not carry out stable disinfection more than 3 times per month. These professionals should not use Iodine products for additional purposes.

With regard to the dietary risk assessment one BPC member questioned the approach to consider iodine coming from other sources via dietary intake when specifying the personal protective equipment. This results in higher requirements regarding the prescribed PPE compared with only considering the biocidal application. In the view of this member, this approach does not suit to the approach taken for the risk assessment where only the biocidal sources are considered to decide whether there is a safe use. This point was however not discussed as ECHA clarified at one of the previous BPC meetings (BPC-26) that the same approach was already taken for earlier Union authorisations containing iodine/PVP-iodine. It was agreed to reflect the BPC member's opinion in the minutes.

In general, with regards to the ED assessment, ECHA will consider the addition of a relevant part in the PAR template. Furthermore, with regards to the BPC opinion template

it was agreed that the Member States should reflect on whether a separate part on the ED assessment or a different heading for the substance of concern should be included.

In addition to the points in the open issues table, one BPC member stressed that the approach taken for the dietary exposure assessment for this particular product family was acceptable, but they don't consider this approach should be used as a precedent for future cases where animal house disinfection is concerned.

ECHA and Commisision reminded that the BPC should avoid asking for post-authorisation data, and should rather conclude based the data already available.

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.

8.2.2 Draft BPC opinion on Union Authorisation application for a product family containing iodine

The Chairman welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The discussion focussed on the items included in the open issues table.

It was discussed whether the evaluation covered both manual and automated application. The BPC agreed that the environmental risk assessment would still need be aligned with previous cases in order to cover the automated applications. Since the default value for automated milking of 3 automated applications was introduced at a later stage, it was not included for this particular assessment. The rapporteur will include the 3 events for the automated scenario in the the environmental risk assessement and amend the PAR, draf SPC and BPC opinion.

With regard to the dietary risk assessment one BPC member questioned the approach to consider iodine coming from other sources via dietary intake when specifying the personal protective equipment. This results in higher requirements regarding the prescribed PPE compared with only considering the biocidal application. In the view of this member, this approach does not suit to the approach taken for risk assessment where only the biocidal sources are considered to decide whether there is a safe use. This point was however not discussed as ECHA clarified at one of the previous BPC meetings (BPC-26) that the same approach was already taken for earlier Union authorisations containing iodine/PVP-iodine. It was agreed to reflect the BPC member's opinion in the minutes.

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 **11 March 2019 (AT)** and **29 March (NL)**.
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.

- **SECR:** to forward the adopted opinions, draft SPCs and final PARs to COM by **25 March 2019 (AT)** and **5 April 2019 (NL)**.
- **SECR**: to forward the translated draft SPCs to COM by **25 April 2019 (AT)** and **5 May 2019 (NL)**.

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

8.3.1 Draft BPC opinion on Union authorisation application for a product family containing propan-2-ol

The Chairman welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The discussion focused on the items included in the open issues table.

For the three Union Authorisation applications based on propan-2-ol, it was agreed to harmonise the SPCs to the extent possible. Related to this it was agreed to list in the SPC all precautionary statements (P-statements) triggered by hazard statements (H-statements). It was also agreed that for Union authorisations the P-statements should be completed in the SPC.

Regarding the content of active substance propan-2-ol in the products, it was agreed that it should be given as weight % (w/w), rather than volume % (v/v) in the SPC. In addition the use description was amended by removing “controlled areas” and clarifying use in cleanrooms. In addition, the contact times were amended to reflect the respective application methods.

For meta-SPC 1 the BPC agreed to state 3 min contact time for yeast for wiping (when the spray product is sprayed to a wipe before its use).

Furthermore, the Committee decided that a maximum number of wipes does not need to be indicated in the SPC as it is was considered not realistic that a professional user takes more wipes as needed.

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.

8.3.2 Draft BPC opinion on Union authorisation application for a product containing propan-2-ol

The Chairman welcomed the applicant for this item. The ASOs were not allowed to be present during the discussion. The discussion focused on the items included in the open issues table.

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. One BPC member (NL) abstained.

8.3.3 Draft BPC opinion on Union authorisation application for a product family containing propan-2-ol

The Chairman welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The discussion focused on the items included in the open issues table.

As indicated above for section 8.3.1, it was agreed to list in the SPC all P-statements triggered by H-statements.

The content of active substance propan-2-ol in the products should be given as % w/w in the SPC. It was also agreed that the P-statements addressing first aid instructions should be given also in section 5.3. of the SPC. In addition the use description was amended by removing “controlled areas” and clarifying use in cleanrooms. This addressed the concern of disinfection of medical devices not being in the scope of the BPR.

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:

- **Rapporteurs:** to revise the product assessment reports (PARs) and draft SPCs in accordance with the discussions in the BPC and submit to the SECR by **11 March 2019**.
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteurs.
- **SECR:** to forward the adopted opinions, draft SPCs and final PARs to COM by **25 March 2019**.
- **SECR**: to forward the translated draft SPCs to COM by **25 April 2019**.

8.4 Working procedure for Union authorisation

SECR presented a proposal to revise the working procedure, namely combining steps 7-9, with the goal to clarify the responsibilities of the eCA during the commenting and trilaterals phases. It also aimed to increase flexibility with the timelines for the upcoming Process Flows. BPC members expressed concerns that the step “disagreement on closing a point” was not foreseen anymore, and requested that 7 days would be reserved for this step. However, BPC members supported the intention to clarify the responsibilities during these steps in the working procedure, and also supported the second proposed change to step 25 of the working procedure.

Actions:

- **SECR:** to finalise the revised working procedure and publish it on the BPC CIRCABC IG and the ECHA website.

8.5 Post authorisation conditions for Union authorisation

The Chairman introduced the document by stating that in the Coordination Group the issue of post authorisation conditions within national authorisation procedures was discussed

resulting in a document agreed at CG-32 entitled “Post authorisation conditions for biocidal products: harmonising practices” (Doc. No. CG-32-2018-16). The present document was prepared by the SECR to describe the practical implementation for the follow-up of post-authorisation conditions for Union authorisation.

The Chairman stated that it is proposed that the main principle and the criteria for including post authorisation conditions are taken over directly from the CG document. This implies that the main principle is that in general post authorisation conditions should always remain an exception and may only be considered on a case by case basis based on these criteria. The Commission strongly supported this recommendation. The meeting agreed to this proposal and some minor comments were made which will be included by the SECR. The SECR agreed to develop the process described in more detail in a future working procedure.

- **SECR:** to upload the document to the BPC CIRCABC IG.

9.1 Draft BPC opinion on an unresolved objection during the notification in accordance with Article 27(1) of the BPR of a PT 19 biocidal product containing peppermint oil and citronellal used to deter feral pigeons

The Chairman welcomed the applicant for this item. The ASOs were not allowed to be present during the discussion.. The ASOs were not allowed to be present during the discussion. The opinion of the BPC that the efficacy of the biocidal product is sufficiently demonstrated and the product meets the conditions for granting a simplified authorisation laid down in Article 25(d) of the BPR was adopted by majority. One BPC member (DE) filed a minority opinion.

Actions:

- **Member:** to submit the minority position by **7 March 2019**.

  SECR: to revise the draft opinion in accordance with the discussions in the BPC and forward the adopted opinion to COM by **8 March 2019**.

10. Any Other Business

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

The SECR presented the document which concerns the proposal to consult the Forum sub-group on BPR (BPRS) on the enforceability on proposed risk management measures stated in the BPC opinions. Two possibilities for the potential consultation were introduced and discussed by the Committee. Several members expressed the view that both options as presented in the document would be supported. Related to option 1 (ad-hoc consultation of the BPRS) the concern was raised that the consultation could delay the process which should be avoided. The Commission noted that the possible involvement of the BPRS should not exempt BPC members, and biocides CAs in general, to develop more knowledge

with their experts on the reality of the biocides market, the use of biocidal products and the related risk mitigation measures. The details of the process would need to be clarified.

Actions:

- **SECR:** to revise the document and publish it on the BPC CIRCABC IG.
- **SECR:** to inform the Forum BPRS of the results of the BPC discussion and report on the Forum BPRS discussion at the next BPC meeting.

10.2 Issue raisded by one MS on External spraying devices

One BPC member presented a document on external spraying devices, and posed questions to the BPC related to the potential need of developing parameters/standards for those devices. The reason for this question is a decion of the Working Group APCP to allow under certain conditions waiving of the MMAD (Mass Median Aerodynamic Diameter) which is a data requirement for droplets/aerosol generating products. One of these conditions is that the biocidal product is sold separately from a spraying device. Several members expressed their views and indicated that currently there is no need to develop specific standards for this purpose.

One member stated that they have in general a problem with demanding MMAD data also for products which are sold together with a spraying device, as the spray head is not specified in the SPC and can be replaced after authorisation. That is why they consider MMAD data as only “nice-to-have-data”.

11. 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 29th meeting of BPC

26 February – 1 March 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-28	
The revised version of the minutes of BPC-28 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) to the SECR by **8 March 2019.**
6.3 Outlook for BPC	
-	-
6.4 Status harmonised classification and labelling for active substances	
-	
6.5. Status ED assessment for active substances	
-	**Members:** to provide comments on the overview by **8 March 2019**.

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 discussed the document.	-
7.2 Draft BPC opinion on metofluthrin for PT 19	
The BPC did not agree on the draft opinion and Assessment Report for the approval of the active substance PT combination due to Article 19(4)(b) and the groundwater risk assessment. Additionally, as the draft opinion did not contain an assessment of the ED criteria the opinion could not be adopted.	**SECR:** to consult with COM on Article 19(4)(b). **Rapporteur:** to perform the groundwater risk assessment and ED assessment and return the opinion and Assessment Report to ECHA.
7.3 Draft BPC opinion on azamethiphos for PT 18	
The BPC did not agree on the draft opinion and Assessment Report for the approval of the active substance PT combination due to the PBT assessment. Additionally, as the draft opinion did not contain an assessment of the ED criteria the opinion could not be adopted.	**Rapporteur:** to perform the PBT and ED assessment and return the opinion and Assessment Report to ECHA.
7.4 Draft BPC opinion on carbendazim for PT 9	
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 **12 April 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 **19 March 2019** and publish it on the ECHA website.
7.5 Revised Assessment Report following the submission of data after active substance approval	
7.5.1 Peracetic acid generated from TAED and sodium percarbonate for PT 2, 3 and 4	
The member from FI informed the BPC about the evaluation of the data submitted after the approval. The BPC agreed with the evaluation of the data by FI.	**Member (FI):** to forward the revised assessment report with the List of Endpoints to the SECR by **19 March 2019.**
7.6 Systematic literature review for ED assessment	
The BPC agreed on the proposal.	**SECR:** to revise the document and publish it on BPC CIRCABC IG.
7.7 Biocides assessment and RAC opinion on harmonised classification (CLH)	

The BPC agreed on the proposal.	**SECR:** to revise the document and publish it on BPC CIRCABC IG. **SECR**: to amend the working procedure for active substance approval.
7.8 Interpreting the definition of relevant impurities	
The BPC discussed the proposal.	**SECR:** to prepare a revised document and open a Newsgroup for commenting on the proposal by **29 March 2019**
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 Draft BPC opinions on Union authorisation applications for a product family containing iodine / PVP-iodine	
The BPC adopted by consensus two opinions 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 **11 March 2019 (AT)** and **29 March (NL)**. **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinions, draft SPCs and final PARs to COM by **25 March 2019 (AT)** and **5 April 2019 (NL)**. **SECR**: to forward the translated draft SPCs to COM by **25 April 2019 (AT)** and **5 May 2019 (NL)**.
8.3 Three draft BPC opinions on Union authorisation applications for a product family containing propan-2-ol	
The BPC adopted by consensus the opinions for the authorisation of the application for Union authorisation.	**Rapporteurs:** to revise the product assessment reports (PARs) and draft SPCs in accordance with the discussions in the BPC and submit to the SECR by **11 March 2019**. **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteurs. **SECR:** to forward the adopted opinions, draft SPCs and final PARs to COM by **25 March 2019**. **SECR**: to forward the translated draft SPCs to COM by **25 April 2019**.
8.4 Working procedure for Union authorisation	

The BPC agreed on the proposal, where the step "disagreement to close a point" will be added.	**SECR**: to finalise the revised working procedure and publish it on the BPC CIRCABC IG and the ECHA website.
8.5 Post authorisation conditions for Union authorisation	
The BPC agreed on the proposal.	**SECR:** to upload the document to the BPC CIRCABC IG.
Item 9 – Article 38 opinions	
9.1 Draft BPC opinion on an unresolved objection during the notification in accordance with Article 27(1) of the BPR of a PT 19 biocidal product containing peppermint oil and citronellal used to deter feral pigeons	
The BPC adopted by majority the opinion.	**Member (DE):** to submit the minority position by **7 March 2019**. **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and forward the adopted opinion to COM by **8 March 2019**.
Item 10 –Any other business	
10.1 Consultation Forum sub-group on BPR (BPRS) on risk management measures	
The BPC discussed the document.	**SECR:** to revise the document and publish it on the BPC CIRCABC IG. **SECR:** to inform the Forum BPRS of the results of the BPC discussion.
10.2 Document on external spraying devices for biocidal products	
The BPC discussed the document.	**Member (BE):** to consider if a document will be prepared for discussion at the BPC.

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Part III - List of Attendees

Members	European Commission
BORGES Teresa (PT)	CHATELIN Ludovic (DG SANTE)
BROVKINA Julija (LV)	
COSTIGAN Michael (UK)	**Advisers**
DRAGOIU Simona (RO)	GOTTLOB Kathrin (DE)
GAVRIEL Alexandros (CY)	HOLTENRICH Dagmar (DE)
GONZALEZ MARQUEZ Maria Luisa (ES)	JOHANSSON Per (SE)
GREGERSEN Nina Falk (DK)	KARHI Kimmo (FI)
HADAM Anna (PL)	KRAUS Sabrina (DE)
HAHLBECK Edda (SE)	SCHNEIDER Heiko (DE)
HAKAITE Palmira (LT)	VISSER Alette (NL)
JAGER Stefanie (DE)	WEINHEIMER Viola (DE)
JOHN Nina (AT)	
KOIVISTO Sanna (FI)	**Accredited Stakeholder Observers**
LANS Martine (NL)	DREVE Simina (FECC)
MERISTE Anu (EE)	MIHAI Camelia (CEFIC)
MIKOLASKOVA Denisa (SK)	
RANDALL Marit (NO)	**ECHA Staff**
RUSCONI Manuel (CH)	AIRAKSINEN Antero
SZANTO Emese (HU)	BARANSKI Maciej
VAGIAS Vasileios (EL)	ESTEVAN MARTINEZ Carmen
VAN BERLO Boris (BE)	GUTIERREZ ALONSO Simon
VRHOVAC FILIPOVIC Ivana (HR)	JANKA Adel
	KREBS Bernhard
Alternate members	KURONEN Terhi
CARBERRY Stephen (IE)	KUSTER Jonathan
COLLET Romy (FR)	MATTHES Jochen
ENSCH Svenja (LU)	MULLER Gesine
MALLIA Lothar Paul (MT)	MYOHANEN Kirsi
MIKOLAS Jan (CZ)	PRIHA Outi
TERNIFI Vesna (SI)	RODRIGUEZ UNAMUNO Virginia
	RUGGERI Laura

	SCHIMMELPFENNIG Heike
	SZYMANKIEWICZ Katarzyna
	VAN DE PLASSCHE Erik
	VAN DER LINDEN Sander
	WEBER Jan
Applicants	**Apologies**
Applied Biocide GmbH	RUBBIANI Maristella (IT)
BELGAGRI SA	
Bird Free Ltd.	
BouMatic	
Contec Cleanroom (UK) Ltd	
CVAS Development GmbH	
Pal International Limited	
Sumitomo Chemical (UK) Plc	

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-29

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-29 meeting

Meeting documents		
Agenda Point	**Number**	**Title**
2	BPC-A-29-2018_rev1	Draft agenda
4	BPC-M-28-2018	Draft minutes from BPC-28
5.2	-	Administrative issues and report from the other Committees
6.1	BPC-29-2018-02	BPC Work Programme 2018-2019
6.2	BPC-29-2018-03	BPC Work Programme 2018-2019 for Union Authorisation
6.3	BPC-29-2018-04	Outlook for the BPC
6.4	-	Status harmonised classification and labelling for active substances
6.5	BPC-29-2018-06	Status ED assessment for active substances
7.1	Procedural and administrative aspects:	
	BPC-29-2018-07	7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval
7.5	Revised Assessment Report following the submission of data after active substance approval:	
	-	7.8.1. Peracetic acid for PT 1- 6, 11 and 12
7.6	BPC-29-2019-12	Systematic literature review for ED assessment
7.7	BPC-29-2019-13	Biocides assessment and RAC opinion on harmonised classification (CLH)
7.8	BPC-29-2019-14	Interpreting the definition of relevant impurities
	BPC-29-2019-25_Room doc 2	
8.4	BPC-29-2019-22	Working procedure for Union authorisation
8.5	BPC-29-2019-23	Post authorisation conditions for Union authorisation
10.1	BPC-29-2019-21	Consultation Forum sub-group on BPR (BPRS) on risk management measures

10.2	BPC-29-2019-26_Room doc 3	Room document (submitted by BE) on external spraying devices	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.2	BPC-29-2019-08A	Metofluthrin - PT 19	Draft BPC opinion
	BPC-29-2019-08B		Assessment report
	BPC-29-2019-08C		Open issues
7.3	BPC-29-2019-09A	Azametiphos - PT 18	Draft BPC opinion
	-		Assessment report
	BPC-29-2019-09C		Open issues
7.4	BPC-29-2019-10A	Carbendazim - PT 9	Draft BPC opinion
	BPC-29-2019-10B		Assessment report
	BPC-29-2019-10C		Open issues
8.2	BPC-29-2019-15A	UA: product families containing iodine / PVP-iodine	Draft BPC opinion
	BPC-29-2019-15B		SPC
	BPC-29-2019-15C		PAR
	BPC-29-2019-15C_Rev1		Revised PAR
	BPC-29-2019-15C1		Conf annex to PAR
	BPC-29-2019-15C1_Rev1		Revised Conf annex to PAR
	BPC-29-2019-15C2		MS Conf annex to PAR
	BPC-29-2019-15C2_Rev1		Revised MS Conf annex to PAR
	BPC-29-2019-15D		Open issues
	BPC-29-2019-15E		Outcome of the APCP e-consultation
	BPC-29-2019-15F		Outcome of the HH e-consultation
	BPC-29-2019-16A	UA: product families containing iodine / PVP-iodine	Draft BPC opinion
	BPC-29-2019-16B		SPC
	BPC-29-2019-16C		PAR
	BPC-29-2019-16C1		Conf annex to PAR
	BPC-29-2019-16C2		MS Conf annex to PAR
	BPC-29-2019-16D		Open issues
	BPC-29-2019-24_Room doc 1		Room doc 1: Appl message to open issues
8.3	BPC-29-2019-17A	UA: product family containing propan-2-ol	Draft BPC opinion
	BPC-29-2019-17B		SPC

	BPC-29-2019-17C		PAR
	BPC-29-2019-17C_Rev1		Revised PAR
	BPC-29-2019-17D		Open issues
	BPC-29-2019-18A	UA: product family containing propan-2-ol	Draft BPC opinion
	BPC-29-2019-18B		SPC
	BPC-29-2019-18C		PAR
	BPC-29-2019-18C_Rev1		Revised PAR
	BPC-29-2019-18C1		Conf annex to PAR
	BPC-29-2019-18D		Open issues
	BPC-29-2019-19A	UA: product family containing propan-2-ol	Draft BPC opinion
	BPC-29-2019-19B		SPC
	BPC-29-2019-19C		PAR
	BPC-29-2019-19C_rev1		Revised PAR
	BPC-29-2019-19D		Open issues
9.1	BPC-29-2019-20	Unresolved objection during the notification in accordance with Article 27(1) of the BPR of a PT 19 biocidal product containing peppermint oil and citronellal used to deter feral pigeons	Draft BPC opinion

15 February 2019
BPC-A-29-2019_rev1

Draft agenda

29th meeting of the Biocidal Products Committee (BPC)

26 February - 1 March 2019

ECHA Conference Centre, Annankatu 18, Helsinki

Starts on 26 February at 09:30, ends on 1 March at 13:00

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-29-2019_rev1

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-28

BPC-M-28-2018

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-29-2019-02

For information

6.2. BPC Work Programme for Union authorisation

BPC-29-2019-03

For information

6.3. Outlook for BPC

BPC-29-2019-04

For information

6.4. Status harmonised classification and labelling for active substances

For information

6.5. Status ED assessment for active substances

BPC-29-2019-06

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-29-2019-07

For information

7.2. Draft BPC opinion on metofluthrin for PT 19

Previous discussion(s): WG-V-2018

BPC-29-2019-08A, B, C

For agreement

7.3. Draft BPC opinion on azametiphos for PT 18

Previous discussion(s): WG-III-2016

BPC-29-2019-09A, B, C

For agreement

7.4. Draft BPC opinion on carbendazim for PT 9

Previous discussion(s): WG-II-2015

BPC-29-2019-10A, 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).

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

7.5.1. Peracetic acid generated from TAED and sodium percarbonate for PT 2, 3 and 4

For agreement

7.6. Systematic literature review for ED assessment

BPC-29-2019-12

For agreement

7.7. Biocides assessment and RAC opinion on harmonised classification (CLH)

BPC-29-2019-13

For agreement

7.8. Interpreting the definition of relevant impurities

BPC-29-2019-14

For agreement

Item 8 – Union authorisation[**]

8.1 Update on Union authorisation

For information

8.2 Draft BPC opinions on Union authorisation applications for a product family containing iodine / PVP-iodine

Previous discussion(s): WG-VII-2018

BPC-29-2019-15A, B, C, D, E, F

For adoption

BPC-29-2019-16A, 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).

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

Previous discussion(s): WG-VII-2018

BPC-29-2019-17A, B, C, D

For adoption

BPC-29-2019-18A, B, C, D

For adoption

BPC-29-2019-19A, B, C, D

For adoption

8.4 Working procedure for Union authorisation

BPC-29-2019-22

For agreement

8.5 Post authorisation conditions for Union authorisation

BPC-29-2019-23

For agreement

Item 9 – Article 38 opinions

9.1 Draft BPC opinion on an unresolved objection during the notification in accordance with Article 27(1) of the BPR of a PT 19 biocidal product containing peppermint oil and citronellal used to deter feral pigeons

BPC-29-2019-20

For adoption

Item 10 – Any other business

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

BPC-29-2019-21

For discussion

Item 11 – Action points and conclusions

For agreement

Provisional time schedule for the

29th meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Annankatu 18, Helsinki

26 February 2019: starts at 09:30; 1 March 2019 ends at 13:00

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 26 February: 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
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 metofluthrin for PT 19	

Tuesday 26 February: afternoon session

Item 7.2	(conti'd)	
Item 7.3	Draft BPC opinion on azametiphos for PT 18	
Item 7.5	Revised Assessment Report following the submission of data after active substance approval:	
	7.5.1.	Peracetic acid generated from TAED and sodium percarbonate for PT 2, 3 and 4
Item 7.6	Systematic literature review for ED assessment	
Item 7.7	Biocides assessment and RAC opinion on harmonised classification (CLH)	
Item 7.8	Interpreting the definition of relevant impurities	

Wednesday 27 February: morning session

Item 7.4	Draft BPC opinion on carbendazim for PT 9
Item 8.1	Update on Union authorisation
Item 8.4	Working procedure for Union authorisation
Item 8.5	Post authorisation conditions for Union authorisation

Wednesday 27 February: afternoon session

Item 8.2	Draft BPC opinions on Union authorisation applications for a product family containing iodine / PVP-iodine

Thursday 28 February: morning session

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

Thursday 28 February: afternoon session

Item 8.3	(conti'd)

Friday 1 March: morning session

Item 9.1	Draft BPC opinion on an unresolved objection during the notification in accordance with Article 27(1) of the BPR of a PT 19 biocidal product containing peppermint oil and citronellal used to deter feral pigeons
Item 10	AOB
Item 11	Action points and conclusions

End of meeting

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