3 October 2017

BPC-M-21-2017

Minutes of the 21st meeting of the Biocidal Products Committee (BPC)

27-29 June 2017

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chairman of the Biocidal Products Committee (BPC) welcomed the participants to the 21th BPC meeting and informed the meeting of one change occurred in the BPC membership, with the Cypriot member and alternate member swapping their roles.

The Chairman also informed the participants of the upcoming changes in the composition of the BPC Secretariat, with a new scientific officer and new assistant taking up duties in September.

The Chairman then informed the BPC members of the participation of 26 members, including six alternates.

Eleven advisers and two representatives from accredited stakeholder organisations (ASOs) were present at the meeting. One representative from the European Commission also attended the meeting. Apologies were received from two members.

Applicants were present for their specific substances and the details are provided in the summary record of the discussion for the substances and in Part III of the minutes.

2. Agreement of the agenda

The Chairman introduced the final draft agenda (BPC-A-21-2017_rev2) and invited then any additional items. No items were added.

The agenda was then 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-20

The revised confidential and non-confidential draft minutes from BPC-20 (BPC-M-20-2017 and BPC-M-20-2017_CONF), incorporating the comments received from members, were agreed. With regard to the actions following BPC-20, the Chairman noted that most of them have been carried out. In particular, regarding the ongoing guidance development, the Chairman informed the meeting that a reporting format to be used for all Working Groups has been developed and that SECR will report to the following BPC and also to the

Coordination Group and CA meeting. Concerning the discussions on how to deal with low hazard substances where the availability of limited data may still lead to risks (due to the use of high uncertainty factors in the absence of data), the Chairman mentioned that some discussion on substances of plant origin has already taken place at the ENV Working Group, but a more structural approach is needed and further initiatives from ECHA are envisaged after the summer. As for the use of human data, the meeting was informed that the Commission intends to discuss the topic at the CA meeting in September. To follow, the Chairman gave a brief update on the item concerning the assessment of ED properties in light of new ED criteria mentioning that the topic is going to be discussed at the July 4 meeting of the Standing Committee on Plants, Animals, Food and Feed and at the following CA meeting. The Chairman then made reference to the revised templates for the BPC opinion and assessment report distributed for the previous meeting, on which comments were received from a few members, all agreeing to the revisions proposed related to the analysis of alternatives for potential candidates for substitution, but with observations related to the incorporation of the revisions in the combined CAR-CLH report template and to the concerns over the analysis of alternatives, in terms of resources and expertise available in the member states, additional information required with short timelines, contribution of ECHA.

Actions:

- **SECR:** to upload the agreed minutes from BPC-20 to the BPC CIRCABC IG and to the ECHA website (the non-confidential minutes) 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 introduced document BPC-21-2017-01 covering the administrative updates and the report form the other ECHA Committees, provided to members for information purposes.

6. Work Programme for BPC

6.1 BPC Work Programme 2017-2018

6.2 Outlook for the BPC

The Chairman presented the revised Work Programme, mentioning that this version is a revised version of the previously disseminated one, following consultations with the MSCAs.

With regard to the outlook for the BPC, the Chairman stated that, according to the current planning, the foreseen number of the opinions for the Review Programme to be adopted this year is below the target of fifty per year and he expressed again the concerns of SECR about not meeting the objective.

The Chairman then mentioned that for the Union authorisation applications it is foreseen to have the first two opinions adopted at the last meeting of 2017 and another three opinions are likely to be adopted at the first meeting of 2018. The Chairman noted that, similarly to the active substance approval process, the delays in the expected submissions by the eCAs cause difficulties in planning and he informed the meeting that the concerns about the delays in the two processes will be discussed at the CA meeting in July.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) to the SECR **by 7 July 2017**.
- **SECR**: on the basis of the changes to update the work programme on the ECHA web site and in the BPC CIRCABC IG.
- **SECR:** to initiate horizontal discussions, for example between the Working Groups, on setting priorities to reduce the workload (related for example to additional information requirements or further assessments where the additional information is not absolutely necessary for the decision making of the approval).

7. Applications for approval of active substances

7.1 Draft BPC opinion on MBIT for PT 6

The Chairman welcomed the applicant for this item. The rapporteur introduced the substance and the general issues related to the assessment report (AR) and the opinions were then discussed in detail (modifications are described in the open issues table).

The BPC discussed the need of PPE during all phases of the application. The Rapporteur indicated that the biocidal product does not show skin corrosion or sensitisation properties. Therefore, the use of PPE is recommended during the mixing and loading phase and necessary during the spraying application to reduce the exposure via dermal route.

A proposal to include a provision limiting the concentration of MBIT in treated articles to not exceed the threshold value set for sensitising properties was not supported since in view of the assessment no risk was identified. It was also agreed not to include a data requirement for analytical methods for body fluids and tissues pending the RAC opinion on this active substance.

The assessment report was agreed by the BPC. The BPC opinion on the approval of MBIT for PT6 was adopted by majority. The member from Germany will submit a minority opinion as they did not support the setting of reference values agreed by the Human Health Working Group.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **11 August 2017.**
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **Member:** to submit the minority position by **7 July 2017**.
- **SECR:** to forward the adopted opinion to COM by **18 July 2017** and publish it on the ECHA website.

7.2 Draft BPC opinion on cholecalciferol for PT 14

The Chairman welcomed the applicant for this item. The rapporteur introduced the substance and the general issues related to the assessment report (AR) and the opinions were then discussed in detail (modifications are described in the open issues table).

The Committee agreed to include the conclusions, and major elements of the discussion, of the RAC opinion in the Assessment Report.

The main point for discussion was the primary and secondary poisoning of birds and mammals and whether mitigation measures exist to control those risks. The assessment is based on the agreed models available (as laid down in the Emission Scenario Document for PT 14) where the results show there are (very) high risks. It was mentioned that the risk for secondary poisoning may in reality be lower as the substance is for example naturally occurring and not expected to accumulate in the food chain. However, at present no robust scientific evidence is available and/or presented in the evaluation. For primary poisoning it was mentioned that risks may be mitigated by introducing risk management measures like tamper resistant bait boxes. However, it was stated that these measures may not prevent primary poisoning from occurring for animals similar or smaller in size compared to rats and mice. Reference was also made to cases of dog poisoning. It was concluded that no safe use can be identified and that biocidal products can only be authorised by relying on Article 19(5). The process of applying Article 19(5) will first need to be clarified by the Commission as this is the first case where the issue arise.

The majority of the BPC members supported the view that due to the unacceptable risks for primary and secondary poisoning cholecalciferol should be considered as meeting Article 10(1)(e) of the BPR. Here it was argued that a more horizontal discussion on the application of this article may be required once the opinion is forwarded to the Commission, as in this case probably all rodenticides do meet this criterion. A parallel was drawn with PT 21 active substances where certain risks were considered acceptable.

It was mentioned that compared to the anticoagulant rodenticides, cholecalciferol has a ‘better’ profile and has a different mode of action which may be important related to the occurrence of resistance. However, it was mentioned that this is not of relevance here but more for a comparative assessment.

It was concluded that the rapporteur would discuss bilaterally with the SECR in order to define whether additional soil biodegradation studies are necessary, taking into account the outcome of the ENV Working Group and PBT expert group on the PBT status of cholecalciferol.

It was also discussed whether the conditions of use indicated in the draft opinion in terms should be harmonised with those of the anticoagulant rodenticides. There was general support to do so, for example by distinguishing between the use categories general public, professionals and trained professionals and by introducing a maximum package size for the general public.

Since the Committee concluded that the active substance meets Article 10(1)(e) of the BPR and is therefore a candidate for substitution, a public consultation will be launched by ECHA. The outcome of this public consultation will be incorporated into a revised BPC opinion to be re-discussed by the Committee.

Actions:

- **SECR:** to launch the public consultation.
- **Rapporteur:** to revise the opinion including the outcome of the public consultation.
- **COM:** to clarify further the procedure for Article 19(5) of the BPR.

7.3 Draft BPC opinion on imiprothrin for PT 18

The Chairman welcomed the applicant for this item. The rapporteur introduced the substance and the general issues related to the assessment report (AR) and the opinions were then discussed in detail (modifications are described in the open issues table).

On the particular point on the data gap related to reference biocidal product (open issues table, issue 9), UK and DE agreed on the need to add the data requirement in a separate chapter in the AR instead of 2.1.1, since it does not only relate to identity.

Finally the members discussed the comment from a member on the reference specification and the comparison to the toxicological batches. It was concluded that further information will be required under section 2.5 to enable the assessment on whether the batches used in the toxicological tests are covered by the reference specification.

The assessment report was agreed by the BPC. The BPC opinion on the approval of imiprothrin for PT18 was adopted by majority. The member from Sweden will submit a minority position due to disagreement over the evaluation of mutagenicity.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **11 August 2017**.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **Member:** to submit the minority position by **7 July 2017**.

- **SECR:** to forward the adopted opinion to COM by **18 July 2017** and publish them on the ECHA website.

7.4 – 7.5 Draft BPC opinion on MBO for PT 2, 6, 11, 12 and 13 and on HPT for PT 2, 6, 11 and 13

The Chairman welcomed the applicant for this item. The rapporteur introduced the substance and the general issues related to the assessment report (AR) and the opinions were then discussed in detail (modifications are described in the open issues table).

The Chairman started by noting that these substances meet the exclusion criteria where the draft CAR was submitted to ECHA after September 2013. The application of the derogation according to Article 5(2) of the BPR is however not in the remit of the BPC but of the Commission in consultation with the Standing Committee of Biocidal Products. He also noted that the renaming of the active substance MBO as reaction products of para-formaldehyde and 2-hydroxy-propylamine (ratio 3:2) and of HPT as reaction products of para-formaldehyde and 2-hydroxy-propylamine (ratio 1:1), is not regarded as a redefinition according to Article 11 of the Review Regulation.

The particular point on the safe uses for PT 2, 6 and 13 (MBO and HPT) (open issues table, issue 30) was extensively discussed by the Committee.

Several members expressed the opinion that while monitoring data can be used to assess if the risk mitigation measures (RMM) in place are working, it cannot be considered a RMM itself. The Rapporteur confirmed that the limit of 40 mg/L of formaldehyde in the effluent of the off-site waste water treatment was not meant to be a RMM and further clarified that 40 mg/L is the detection limit, being the reason why the value was used in the calculations.

It was discussed whether it would be possible to either include concrete RMM or, in the absence of RMM, impose a limit of 40 mg/L of formaldehyde in the effluent of the off-site waste water treatment, including it in section 2.3 of the opinion, as a condition, followed by the inclusion in section 2.4 of the request to provide monitoring data at product authorisation stage to confirm that the emission limit is met. Some members showed concern to impose limits for the effluents of users of the biocidal products.

The SECR noted that companies dealing with hazardous waste have their own permits already. It was furthermore indicated to have been agreed at the Environment Working Group that one monitoring study is not sufficient to quantify a risk, but it could be used to show evidence of the effectiveness of the treatment in removing formaldehyde. Also, it was highlighted that one outcome of the ad-hoc follow-up of the Environment Working Group was the request for an STP simulation test to show the complete mass balance and prove that no further risk mitigation measures are needed.

The Chairman highlighted that with all the evidence in place, including the fact that no degradation was assumed in the assessment, it could be concluded that the assessment was over-conservative. It was decided to amend the opinions in this way, include a standard condition and element for product authorisation and require further information including possibly a STP simulation test.

In view of the several changes needed in the Opinion, and indicated by the Chairman, the Rapporteur reworked the Opinions and these were presented to the Committee on the following day.

Another point discussed was the exceedance of the trigger value of 0.1 µg/l for 2-HPA and formaldehyde, for PT 2, 6, 11 and 13. This is related to Annex VI, mentioning 0.1 µg/l as the maximum permissible concentration in the abstraction of surface water for production of drinking water. It was noted that this is the first time that the issue is raised.

The SECR highlighted the importance of clarifying this point since for many substances evaluated so far, for which only the PEC for ground water was compared with the trigger value of 0.1 µg/l, the PEC for surface water would also exceed the trigger value. The Commission stated that further reflection would be needed on this matter. The Chairman proposed to keep the statement in the opinion for information as an element to be taken into for product authorisation. In addition, the issue of the implementation of paragraph 69 in Annex VI will require a separate discussion, both on technical and regulatory aspects.

Finally the question was raised on whether the AR should cover Article 5(2), noting that here the AR contains a whole section dedicated to this matter. The Commission welcomed the work already done by the Rapporteur but clarified that the process underlined by Article 5(2) is not in the remit of the BPC but is further analysed during the decision making process by the Commission and the Standing Committee on Biocidal products. It was therefore considered by the Committee that being 5(2) out of the remit of the BPC it needs to be ensured that the AR is in line with any decision taken later on by the Commission or to indicate that the relevant sections contains the position of the Rapporteur. Another option would be to remove this element from the AR.

The assessment report was agreed by the BPC. The BPC concluded that MBO used in product-types 2, 6, 11, 12 and 13; and HPT for product-types 2, 6, 11 and 13 should normally not be approved unless one of the conditions for derogation set in Article 5(2) of Regulation (EU) No 528/2012 is met. The opinions were adopted by consensus and with the abstention of the member from SE.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **11 August 2017.**
- **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 to COM by **18 July 2017** and publish them on the ECHA website.

7.6 Draft BPC opinion on copper for PT 2, 5 and 11

The Chairman welcomed the applicant for this item. The rapporteur introduced the substance and the general issues related to the assessment report (AR) and the opinions were then discussed in detail (modifications are described in the open issues table).

The BPC discussed the naming of the substance. A member proposed to use the name copper-ions released from copper by electrolysis because in contrast to other copper compounds here the substance is not a salt and the representative use is an in-situ system. This was supported by some other members. The SECR referred to the REACH guidance, which is applicable here, where it is stated that an ion is not a substance. Also, the SECR indicated that the application is based on an essential use derogation where the name copper is used with the respective CAS and EC number. Redefining the name would create complications in this respect. Other members stated that there are other ways to release copper ions, which would not be covered in case the name would refer to electrolysis. A stakeholder proposed to use the name activated copper as otherwise the same name for the precursor and the active substance is used. Using this name could overcome some concerns and improve regulatory efficiency and be more consistent. The Chairman concluded that the name copper was supported by the majority.

The reference specifications was another subject of discussion. The current reference specifications only covers the use of copper by electrolysis pending the submission of some additional information on the impurities. It was concluded to await this additional information so a reference specification can be set covering all future uses. The rapporteur will revise the opinions, which will then be adopted by written procedure.

It was concluded by the Chairman that a more horizontal discussion is needed on how to set reference specifications and on the assessment on whether the (eco)toxicological data available are covering the reference specification. The SECR will initiate such a discussion.

Actions:

- **Applicant:** to submit information to the eCA related to the specification.
- **Rapporteur:** to revise the opinions based on the information received from the applicant.
- **SECR:** to launch the written procedure for the adoption of the opinions.

7.7 Outcome of the written procedure on cypermethrin for PT 18

The Chairman informed the meeting about the outcome of the written procedure on the adoption of the opinion for cypermethrin in PT 18. The opinion was adopted in this procedure, where minor comments made during the written procedure have been incorporated.

7.8 Revised Assessment Report following the submission of data after active substance approval for the renewal of difenacoum PT 14

The rapporteur presented their response to comments from several members related to the evaluation of confirmatory data submitted after the renewal of the approval of difenacoum in PT 14. It was concluded that the submitted quality control data for the individual sources confirm the validity of the existing specifications.

Actions:

- **Rapporteur:** to revise the Assessment Report and forward it to the **SECR**
- **SECR:** to disseminate the revised AR on CIRCABC and on the ECHA website.

7.9 Catalogue of standard phrases for active substance approval

The SECR presented the amendments to the catalogue of standard phrases and invited the members to use these phrases in future opinions.

8. Union authorisation

8.1 Update on Union authorisation

The item was not presented.

Actions:

- **SECR** to distribute the presentation via CIRCA BC.

8.2 Timelines for the peer review process for applications for Union authorisation

The item was postponed to the next BPC meeting in October.

8.3 Revised BPC opinion template for Union authorisation

The item was not presented.

Actions:

- **SECR** to open a Newsgroup on CIRCA BC for written comments.

9. Any other business

9.1 Outcome of the e-consultation on the open items identified at the ENV Working Groups

Three questions coming from Environment WG meetings were send to the BPC for clarification. The discussion of the first and third questions was postponed to the next BPC meeting, only the second question was discussed, i.e "*Can the BPC confirm that all nine scenarios need to show a safe use for Union authorisation? What are the implications for Union authorisation with regard to the authorisation, if not all nine scenarios FOCUS scenarios show a safe use?"*

The BPC confirmed the conclusion of the ENV WG, that all nine FOCUS scenario should show a safe use, since a product authorised by Union Authorisation can be placed on the market in all Member States. However, if this is not the case and the applicability of the models for the substance evaluated can be questioned, a qualitative approach could be applied using expert judgement in a weight of evidence approach.

Actions:

- **SECR:** to report back the BPC conclusion to the ENV WG and to schedule the discussion of the remaining two open questions for BPC-22.

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 21st meeting of BPC

27-29 June 2017

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-20	
The revised version of the confidential and non-confidential minutes of BPC-20 was agreed as proposed subject to several editorial modifications.	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website (the non-confidential minutes) after the meeting.
Item 6 - Work programme for BPC	
6.1 Revised Work Programme 2017-2018 and Outlook for BPC	
	Members: to send information on any further changes to the Work Programme (WP) to the SECR by **7 July 2017.** **SECR:** on the basis of the changes to update the WP on the ECHA website and in the BPC CIRCABC IG. **SECR**: to initiate horizontal discussions, for example between the Working Groups, on setting priorities to reduce the workload (related for example to additional information requirements or further assessments where the additional information is not absolutely necessary for the decision making of the approval).
Item 7 - Applications for approval of active substances	
7.1 Draft BPC opinion MBIT for PT 6	
The BPC adopted by majority the opinion for the approval of the active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **11 August 2017.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **Member:** to submit the minority position by **7 July 2017**.

	SECR: to forward the adopted opinion to COM by **18 July 2017** and publish it on the ECHA website.
7.2 Draft BPC opinion on cholecalciferol for PT 14	
The BPC agreed that due to primary and secondary poisoning Article 10(1)(e) of the BPR is met and therefore cholecalciferol is considered a candidate for substitution. The opinion will be revised following the public consultation.	**SECR:** to launch the public consultation. **Rapporteur:** to revise the opinion including the outcome of the public consultation. **COM:** to clarify further the procedure for Article 19(5) of the BPR.
7.3 Draft BPC opinion on imiprothrin for PT 18	
The BPC adopted by majority the opinion for the approval of the active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **11 August 2017.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **Member:** to submit the minority position by **7 July 2017**. **SECR:** to forward the adopted opinion to COM by **18 July 2017** and publish it on the ECHA website.
7.4 Draft BPC opinion on Reaction product of para-formaldehyde and 2-hydroxy-propylamine (ratio 3:2) for PT 2, 6, 11, 12 and 13	
The BPC adopted by consensus the opinions of the active substance/PT combinations. Since the active fulfils the criteria set in Article 5(1) of the BPR, the overall conclusion is that the active/PT combinations should normally not be approved, unless one of the conditions for derogation in Article 5(2) of the BPR is met. The substance is considered a candidate for substitution in accordance with Article 10(1)(a) of the BPR. One member abstained.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **11 August 2017.** **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 to COM by **18 July 2017** and publish them on the ECHA website.
7.5 Draft BPC opinion on Reaction product of para-formaldehyde and 2-hydroxy-propylamine (ratio 1:1) for PT 2, 6, 11 and 13	
The BPC adopted by consensus the opinions of the active substance/PT combinations. Since the active fulfils the criteria set in Article 5(1) of the BPR, the overall conclusion is that the active/PT combinations should normally not be approved, unless one of the conditions for derogation in Article 5(2) of the BPR is met. The substance is considered a candidate for substitution in accordance with Article 10(1)(a) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **11 August 2017.** **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 to COM by **18 July 2017** and publish them on the ECHA website.

One member abstained.	
7.6 Draft BPC opinion on copper for PT 2, 5 and 11	
The BPC will adopt the opinions for the approval of the active substance/PT combinations by written procedure.	**Applicant:** to submit information to the eCA related to the specification. **Rapporteur:** to revise the opinion based on the information received from the applicant. **SECR:** to launch the written procedure for the adoption of the opinion.
7.7 Outcome of the written procedure on cypermethrin for PT 18	
The SECR informed the meeting on the outcome of the written procedure in which the opinion for cypermethrin for PT 18 was adopted.	
7.8 Revised AR following the submission of data after active substance approval for the renewal of difenacoum for PT 14	
The BPC agreed to evaluation of the eCA of the data received after the renewal of the approval of difenacoum for PT 14.	**Rapporteur:** to revise the AR. **SECR:** to disseminate the revised AR on CIRCABC and on the ECHA website.
7.9 Catalogue of standard phrases for active substance approval	
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Item 8 – Union authorisation	
8.1 Update on Union authorisation	
The agenda item was not discussed.	
8.2 Timelines for the peer review process for applications for Union authorisation	
The agenda item was postponed to BPC-22.	
8.3 Revised BPC opinion template for Union authorisation	
The agenda item was not discussed.	**SECR:** to open a Newsgroup for written comments.
Item 9 – AOB	
9.1 Outcome of the e-consultation on the open items identified at the ENV Working Groups	
Concerning question 2: the BPC confirmed that all nine FOCUS scenario should be safe. However, a qualitative approach should be applied using expert judgement in a case by case assessment. The other two questions will be discussed at the next BPC meeting.	

Part III - List of Attendees

Members	European Commission
BORGES Teresa (PT)	CHATELIN Ludovic (DG SANTE)
BROVKINA Julija (LV)	
CABALLO DIÉGUEZ Covadonga (ES)	**Advisers**
ČEBAŠEK Petra (SI)	ALTMANN Dominik (AT)
CHÉZEAU Aurélie (FR)	DOLINSKA Tatiana (PL)
COSTIGAN Michael (UK)	GOUR Annabelle (FR)
DRAGOIU Mihaela-Simona (RO)	HADAM Anna (PL)
GAVRIEL Alexandros (CY)	HYVÄRINEN Tuija (FI)
HAHLBECK Edda (SE)	KORKOLAINEN Tapio (FI)
JÄGER Stefanie (DE)	STANG Christopher (DE)
KOIVISTO Sanna (FI)	UJMA-CZWAKIEL Monika (PL)
KOMEN Corine (NL)	WEINHEIMER Viola (DE)
LARSEN Jørgen (DK)	
MERISTE Anu (EE)	
MIKOLASKOVA Denisa (SK)	
SZANTÓ Emese (HU)	**Accredited Stakeholder Observers**
VACEK Tomas (CZ)	MIHAI Camelia (CEFIC)
VAN BERLO Boris (BE)	MONTMOREAU Bertrand (CEPA)
VRHOVAC FILIPOVIC Ivana (HR)	BAKEN Stijn (ECI)
ZOUNOS Athanasios (EL)	**ECHA Staff**
	ESTEVAN MARTINEZ Carmen
Alternate members	JANOSSY Judit
CRESTI Raffaella (IT)	KREBS Bernhard
DONS Christian (NO)	NEGULICI Ligia
ENSCH Svenja (LU)	NOGUEIRO Eugénia
HUSZAL Sylwester (PL)	SAEZ RIBAS Monica
PÜRGY Reinhild (AT)	SCHIMMPELPFENNIG Heike
PYTHON François (CH)	VAN DE PLASSCHE Erik

Applicants	Apologies
DZIK Ewa (Dow Europe GmbH) for MBIT PT 6	BROWN Finbar (IE)
FRISCH Anja (Schülke & Mayr GmbH) for MBO and HPT	GIORDMAINA Wayne (MT)
KRULL Ingo (Schülke & Mayr GmbH) for MBO and HPT	
MARTIN Robert (Sumitomo Chemical (UK) Plc) for imiprothrin PT 18	
McGRATH Michael (Task force copper) for copper PT 2, 5 and 11	
RENAULT-BILLAULT Dominique (Bayer SAS) for cholecalciferol PT 14	
SHARPLES Roger (BASF) for cholecalciferol PT 14	
Experts accompanying applicants	
HAHN Stefan, accompanying KRULL Ingo and FRISCH Anja, for MBO and HPT	
HOWARD Karen, accompanying RENAULT-BILLAULT Dominique and SHARPLES Roger, for cholecalciferol PT 14	
MACKIE Carol, accompanying McGRATH Michael, for copper PT 2, 5, 11	
RUSTED Jamie, accompanying MARTIN Robert, for imiprothrin PT 18	
VALLOTTON Nathalie, accompanying DZIK Ewa for MBIT PT 6	

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-21

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-21 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2	BPC-A-21-2017	Draft agenda	
4	BPC-M-20-2017	Draft minutes from BPC-20	
5.2	BPC-21-2017-01	Administrative issues and report from the other Committees	
6.1	BPC-21-2017-02	BPC updated Work Programme 2017-2018	
6.2	BPC-21-2017-03	Outlook for the BPC	
7.7	BPC-21-2017-20	Outcome of the written procedure on cypermethrin for PT 18	
7.8	BPC-21-2017-21	Revised AR following the submission of new data after AS approval for the renewal of difenacoum PT 14	
7.9	BPC-21-2017-04	Catalogue of standard phrases for AS approval	
8.1	BPC-21-2017-22	Update on Union authorisation	
8.2	BPC-21-2017-23	Timelines for the peer review process for applications for UA	
8.3	BPC-21-2017-24	Revised BPC opinion template for UA	
9.1	BPC-21-2017-25	Outcome of the e-consultation on the open items identified at the ENV Working Groups	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.1	BPC-21-2017-05A	MBIT PT 6	Draft BPC opinion
	BPC-21-2017-05B		Assessment report
	BPC-21-2017-05C		Open issues
7.2	BPC-21-2017-06A	Cholecalciferol PT 14	Draft BPC opinion
	BPC-21-2017-06B		Assessment report
	BPC-21-2017-06C		Open issues
7.3	BPC-21-2017-07A	Imiprothrin PT 18	Draft BPC opinion
	BPC-21-2017-07B		Assessment report

	BPC-21-2017-07C		Open issues
7.4	BPC-21-2017-08A	MBO PT 2	Draft BPC opinion
	BPC-21-2017-08B		Assessment report
	BPC-21-2017-08C		Open issues
	BPC-21-2017-09A	MBO PT 6	Draft BPC opinion
	BPC-21-2017-08B		Assessment report
	BPC-21-2017-08C		Open issues
	BPC-21-2017-10A	MBO PT 11	Draft BPC opinion
	BPC-21-2017-08B		Assessment report
	BPC-21-2017-08C		Open issues
	BPC-21-2017-11A	MBO PT 12	Draft BPC opinion
	BPC-21-2017-08B		Assessment report
	BPC-21-2017-08C		Open issues
	BPC-21-2017-12A	MBO PT 13	Draft BPC opinion
	BPC-21-2017-08B		Assessment report
	BPC-21-2017-08C		Open issues
7.5	BPC-21-2017-13A	HPT PT 2	Draft BPC opinion
	BPC-21-2017-13B		Assessment report
	BPC-21-2017-13C		Open issues
	BPC-21-2017-14A	HPT PT 6	Draft BPC opinion
	BPC-21-2017-13B		Assessment report
	BPC-21-2017-13C		Open issues
	BPC-21-2017-15A	HPT PT 11	Draft BPC opinion
	BPC-21-2017-13B		Assessment report
	BPC-21-2017-13C		Open issues
	BPC-21-2017-16A	HPT PT 13	Draft BPC opinion
	BPC-21-2017-13B		Assessment report
	BPC-21-2017-13C		Open issues
7.6	BPC-21-2017-17A	Copper PT 2	Draft BPC opinion
	BPC-21-2017-17B		Assessment report
	BPC-21-2017-17C		Open issues
	BPC-21-2017-17D		Specifications
	BPC-21-2017-18A	Copper PT 5	Draft BPC opinion
	BPC-21-2017-18B		Assessment report
	BPC-21-2017-17C		Open issues
	BPC-21-2017-17D		Specifications
	BPC-21-2017-19A	Copper PT 11	Draft BPC opinion

	BPC-21-2017-19B		Assessment report
	BPC-21-2017-17C		Open issues
	BPC-21-2017-17D		Specifications

15 June 2017
BPC-A-21-2017_rev2

Final agenda
21st meeting of the Biocidal Products Committee (BPC)
27 – 29 June 2017
ECHA Conference Centre, Annankatu 18, Helsinki
Starts on 27 June at 09:30, ends on 29 June at 13:00

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-21-2017_rev

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-20

BPC-M-20-2017

For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

BPC-21-2017-01

For information

6. – Work programme for BPC

6.1. Revised BPC Work Programme 2017-2018

BPC-21-2017-02

For information

6.2. Outlook for BPC

BPC-21-2017-03

For information

7. – Applications for approval of active substances*

7.1. Draft BPC opinion on MBIT for PT 6

Previous discussion(s): WG-IV-2016

BPC-21-2017-05, A, B and C

For adoption

7.2. Draft BPC opinion on cholecalciferol for PT 14

Previous discussion(s): WG-I-2017

BPC-21-2017-06, A, B and C

For adoption

7.3. Draft BPC opinion on imiprothrin for PT 18

Previous discussion(s): WG-I-2017

BPC-21-2017-07, A, B and C

For adoption

7.4. Draft BPC opinion on MBO (Reaction product of para-formaldehyde and 2-hydroxy-propylamine (ratio 3:2)) for PT 2, 6, 11, 12 and 13

Previous discussion(s): WG-II-2017

PT 2: BPC-21-2017-08A, B and C
PT 6: BPC-21-2017-09A, BPC-21-2017-08B and C
PT 11: BPC-21-2017-10A, BPC-21-2017-08B and C
PT 12: BPC-21-2017-11A, BPC-21-2017-08B and C
PT 13: BPC-21-2017-12A, BPC-21-2017-08B and C

For adoption

7.5. Draft BPC opinion on HPT (Reaction product of para-formaldehyde and 2-hydroxy-propylamine (ratio 1:1)) for PT 2, 6, 11 and 13

Previous discussion(s): WG-II-2017

PT 2: BPC-21-2017-13A, B and C
PT 6: BPC-21-2017-14A, BPC-21-2017-13B and C
PT 11: BPC-21-2017-15A, BPC-21-2017-13B and C
PT 13: BPC-21-2017-16A, BPC-21-2017-13B and C

For adoption

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

7.6. Draft BPC opinion on copper for PT 2, 5 and 11

Previous discussion(s): WG-V-2016

PT 2: BPC-21-2017-17A, B and C
PT 5: BPC-21-2017-18A, B and BPC-21-2017-17C
PT 11: BPC-21-2017-19A, B and BPC-21-2017-17C

For adoption

7.7. Outcome of the written procedure on cypermethrin for PT 18

BPC-21-2017-20

For information

7.8. Revised Assessment Report following the submission of data after active substance approval for the renewal of difenacoum PT 14

BPC-21-2017-21

For agreement

7.9. Catalogue of standard phrases for active substance approval

BPC-21-2017-04

For information

Item 8 – Union authorisation

8.1. Update on Union authorisation

BPC-21-2017-22

For information

8.2 Timelines for the peer review process for applications for Union authorisation

BPC-21-2017-23

For information

8.3 Revised BPC opinion template for Union authorisation

BPC-21-2017-24

For discussion

Item 9 – Any other business

9.1. Outcome of the e-consultation on the open items identified at the ENV Working Groups

BPC-21-2017-25

For agreement

Item 10 – Agreement of the action points and conclusions

For agreement

Provisional timeline for the

21st meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Annankatu 18, Helsinki

27 June 2017: starts at 09:30; 29 June ends at 13:00

Please note that the timings indicated below are provisional and subject to possible change. They are distributed to participants on a preliminary basis.

Tuesday 27 June: morning session

Items 1-5	Opening items and administrative issues
Item 6	Work programme of the BPC 2017-18
Item 7.1	Draft BPC opinion on MBIT for PT 6

Tuesday 27 June: afternoon session

Item 7.2	Draft BPC opinion on cholecalciferol for PT 14
Item 7.3	Draft BPC opinion on imiprothrin for PT 18

Wednesday 28 June: morning session

Item 7.4	Draft BPC opinion on MBO for PT 2, 6, 11, 12 and 13

Wednesday 28 June: afternoon session

Item 7.5	Draft BPC opinion on HPT for PT 2, 6, 11 and 13

Thursday 29 June: morning session

Item 7.6	Draft BPC opinion on copper for PT 2, 5 and 11
Item 7.7	Outcome of the written procedure on cypermethrin for PT 18
Item 7.8	Revised Assessment Report following the submission of data after active substance approval for the renewal of difenacoum PT 14
Item 8.1	Update on Union authorisation
Item 8.2	Timelines for the peer review process for applications for Union authorisation
Item 8.3	Revised BPC opinion template for Union authorisation
Item 9.1	Outcome of the e-consultation on theopen items identified at the ENV Working Groups
Item 10	Agreement of action points and conclusions

End of meeting

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