25 April 2018

BPC-M-24-2018

Minutes of the 24th meeting of the Biocidal Products Committee (BPC)

6-7 March 2018

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chairman of the Biocidal Products Committee (BPC) welcomed the participants to the 24th BPC meeting.

Regarding the BPC membership, the Chairman welcomed the new BPC members from Greece; Vasileios Vagias, from Norway; Berit Randall and from Spain; Maria Luisa Gonzalez Marquez. He stated that there are also new alternate members from Greece; Dimitra Gklipathi, from Norway; Astrid Gaustad and from Spain; Covadonga Caballo Diéguez.

The Chairman then informed the BPC members of the participation of 26 members, including 5 alternates.

7 advisers and 1 representative from accredited stakeholder organisations (ASOs) were present at the meeting. One representative from the European Commission also attended the meeting. Apologies were received from 2 members.

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

2. Agreement of the agenda

The Chairman introduced the final draft agenda (BPC-A-24-2018_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 stated the following would be closed agenda items: Item 6.3, 7.4.2, 8.1 and 8.2.

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-23

The revised draft minutes from BPC-23 (BPC-M-23-2017), incorporating the comments received from members, were agreed.

The Chairman noted that the actions from BPC-23 have been carried out.

The Chairman informed the meeting on:

- Union authorisation and Article 38 applications :

With respect to the adopted opinions on two applications for Union authorisation and one opinion on an Article 38 request from the Commission the Chairman mentioned that these opinions have not been disseminated yet by ECHA. Only once a decision has been taken by the Commission they will be published on the ECHA website.

- new timelines for the active substance approval process and for Union authorisation have been published on the ECHA website. These new timelines contain the following process flows ending with the one leading to the BPC meeting in December 2019.

- also an overview has been created by the SECR containing all timelines for both processes in one Excel table. This was prepared and distributed on request only to the MSCAs via CIRCABC IG for the Working Groups.

- a document which will be presented at the next Management Board meeting on the functioning of the ECHA committees RAC, SEAC, MSC and BPC. The document was prepared following a request from the previous MB meeting. The questions from the MB with respect to the functioning related to issues like the required expertise, participation and activity level of the members.

- the discussion at the last CA meeting on the ED criteria.

Actions:

- **SECR:** to upload the agreed minutes from BPC-23 to the BPC CIRCABC IG and to the ECHA website after the meeting.
- **SECR**: to upload the presentation on the “implementation of the criteria for endocrine-disrupting properties” to BPC CIRCABC IG.

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 informed the members that the Rules of Procedure has been revised and is available on the ECHA website. The RoP were revised as ECHA updated the declaration templates and simplified the declaration procedure. The SECR considers this to be only an administrative revision as it was based on a decision taken at the ECHA Management Board.

The Chairman introduced document BPC-24-2017-01 prepared by ECHA for the Management Board meeting which contains the progress reports for each Committee including the PBT and ED Expert Groups. This document replaces – as announced at the BPC-23 meeting – the previous report for BPC members in this area.

The Commission representative asked ECHA to provide an overview of the status, and planning, for the establishment of harmonised classification of all active substances, of the PBT status and need/state of play of discussions in the PBT expert group, and of the ED status and need/state of play of ED expert group. These are elements of key importance in the review process, and it would be useful to have a good tracking and overview of these elements on active substances. This should be developed and provided to the BPC. ECHA noted the request.

5.3 Mandate of the Ad-hoc Working Group Environmental Exposure

The meeting agreed on a revised mandate for the Ad-hoc Working Group Environmental Exposure (AHEE). It will be added that a) in cases where the AHEE does not come to a consensus, the issue will be forwared to the Working Group Environment and b) stakesholders will be invited as observers.

It was clarified that the increased scope of the mandate of this group is not required for the Ad-hoc Working Group on Human Exposure. The SECR asked the members to review the assignment of their MSCAs in the AHEE to assure an even representation in this group.

6. Work Programme for BPC

6.1 BPC Work Programme 2018-2019

6.2 Outlook for the BPC

The Chairman informed members that the Work Programme was revised after the last BPC meeting and uploaded to BPC CIRCABC IG. A public version was also published on the ECHA website.

The document distributed for this meeting is a revised version following consultations with MSCAs based on information received following the dissemination of the previous version. Members were invited to contact the SECR on possible changes by 16 March 2018 after which a revised version will be published on the ECHA website. Some changes already received are not yet incorporated in this version.

The Chairman stated that:

- For active substance approval the number of adopted opinions based on the published work programme for the Review Programme in 2018 is 54. In addition, 2 BPR new actives and 1 BPD new active is scheduled.

- For Union authorisation the number of scheduled opinions is 19. The Chairman stated that these numbers are per application. The number of product PT combination is 29 for 2018.

The Chairman furthermore stated that:

- The number of draft CARs submitted for the last process flow which ended on March 6 is much lower than scheduled: 19 scheduled but 5 received. This leads to 40 instead of 54 opinions for the Review Programme planned for discussion in 2018.

- Due to the fact that no draft CARs were submitted for several process flows there are no discussions at the Working Group meetings of March and May this year so those meetings may both be cancelled. The BPC meetings will not be cancelled as there are either backlog dossiers or Union authorisations which will be discussed.

Similarly to previous BPC meetings, the Commission voiced concerns on the current plan for work of the BPC in 2018, as only 40 opinions are so far planned this year. Compared to previous years, the plans at the beginning of each year was around 70-80 opinions, with a final delivery at the end of the year of half these numbers (ie. 35-40 opinions). This situation is worrying, and Member States need to deliver and keep their commitments. Discussions continues in the CA meeting and BPC members should take the appropriate actions to improve the situation.

The Commission also stressed again the need for the BPC to improve its opinions concerning the identification of alternatives to substances subject to exclusion and substitution, and this should be done this year for concerned substances planned for discussion. For instance, chlorfenapy PT18 (exclusion criteria) will be reviewed, noting that 47 active substances have already been approved for PT18, and around a thousand of PT18 product authorisations delivered to date; the renewal of approval of creosote PT08 (exclusion criteria), noting that almost all PT08 active substances have already been reviewed and PT08 product authorisations delivered. This was noted by ECHA.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) to the SECR by **16 March 2018**.
- **SECR**: on the basis of the changes to update the work programme on the ECHA website and in the BPC CIRCABC IG.

6.3 New requests from the Commission related to Article 38 and Article 75(1)(g)

The Chairman stated that an Article 38 and Article 75(1)(g) request was received from the Commission and asked the BPC for their opinion and comments on the proposal from the SECR that ECHA acts as the rapporteur for the Article 75(1)(g) request. No comments were made on both requests by the members. It was agreed that ECHA will act as the rapporteur for the Article 75(1)(g) request.

7. Applications for approval of active substances

7.1. Working procedure for active substance approval

The Chairman introduced the main changes in the new proposal for the working procedure for active sustance approval: i) the criteria for accordance check is amended for consultation of PBT and ED EG in the light of experience; ii) the eCA would be responsible for communication with the applicant in the peer review phase with respect to the Working Groups, and iii) stressed the importance of not closing the evaluation task in R4BP 3 until a positive result of the accordance check has been received by the eCA from ECHA, as otherwise no re-submission of a IUCLID dossier from the applicant can take place via R4BP 3.

One member stated that IUCLID dossier re-submission cannot be requested by the eCA during the peer review (ECHA Opinion stage in R4BP 3) and asked for a possible solution. ECHA explained that R4BP 3 does not have an accordance check step, and that requesting IUCLID dossier resubmission during the ECHA opinion stage is rarely needed.

Some BPC members disagreed with the conditions in section 5.1.2 for passing/failing the accordance check on providing the reason for whether one or more of the conditions of Article 5 (2) does apply or not.There was some discussion on the issue, mainly on the fact that this will be a very high burden for eCAs as sufficient information might be not available as public consultion will take place at a later step of the process. Furthermore, under the BPD it was not a data requirement to provide information related to this issue. It was agreed that Commission and ECHA will check whether this is legally required.

One member asked to define the role of an observer in an ad-hoc follow-up which will be adressed in the revised version.

There was also a question, if a new CAR template (to include the ED criteria) will be developed. ECHA appreciated the suggestion and will consider it. One member asked why the responsibility to communicate with the applicant is given back to the eCA where ECHA explained that it has always been their responsibility, although ECHA took over for some steps and highlighted that the eCA has the knowledge of the confidential parts of substance documents in particular when the data package is shared with multiple applicants.

- **SECR:** to finalise, taking into account the comments made at the meeting, and to publish the working procedure on the ECHA website and on BPC S-CIRCABC IG.
- **SECR:** to consult with COM on whether the assessment of Article 5(2) needs to be included in the draft evaluation submitted by the eCA for peer review.

7.2 Draft BPC opinion on salicylic acid for PT 2, 3, 4

The Chairman welcomed the applicant for this item. The rapporteur introduced the substance and the general issues related to the active substance and explained that the evaluation of the active substance had been put on hold until a RAC opinion had been delivered. The assessment report (AR) and the opinion were then discussed in detail (modifications are described in the open issues table).

The Chairman mentioned that the AR documents will be revised including further information, since it had not been fully clear which documents were necessary for the BPC discussion, the CAR being prepared in the new CAR format. The Chairman also mentioned that there is an internal discussion ongoing related to the dissemination of CARs available in the new format.

The Commission noted that the intended use for this active substance in PT 2 is very specific (in particular in PT2 and surprising (i.e. disinfection of dishwashing sponges by the general public) and informed the BPC that further consultations might take place within the Commission regarding the relevance and meaningfulness of this reference biocidal product. More generally, the Commission called for the attention of all eCAs during the preparation, the submission and during the review of an application, and to have discussions with the applicant to ensure that the work performed is meaningfull.

The rapporteur clarified that an assessment of the ED properties according to the new ED criteria has not yet been performed, although for this active substance there is no indication of endocrine-disrupting properties so far. It was clarified that, although the opinion can be adopted, the eCA will have to conclude on the ED assessment according to the new scientific criteria before the Standing Committee on biocidal products can be consulted on a decision. The eCA should therefore start such work without delay.

The BPC members agreed that for the uses under PT2 there was no need to include specific provisions in sections 2.3 and 2.4 of the BPC opinion as regard to indirect exposure via regarding food and feed, which was required for PT3 and PT4.

The Commission asked the applicant about the status of the confirmatory data to be provided 6 months before the approval of the active substance and reminded MSCAs and the applicant that this type data should have been provided well in advance in order to be included in the BPC opinion.

The rest of open issues on the assessment report (AR) and the opinion were afterwards discussed and the modifications are described in the open issues table.

The Assessment Report and the BPC Opinions were adopted by the BPC by consensus, subject to the changes agreed during the meeting.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the BPC Secretariat by **20 April 2018.**
- **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 **28 March 2018** and publish it on the ECHA website.

7.3 Draft BPC opinion on 2-Phenoxyethanol for PT 1, 2, 4

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

The rapporteur clarified that after discussions with the SECR the secondary exposure scenario for toddlers should be revised in line with the Working Group Human Health agreement to use different film thickness values for the skin and for food in contact with treated surfaces. The outcome of this revision is that a rinsing step with 90% efficiency is necessary to have a safe use in the secondary exposure scenario for toddlers in both PT2 and PT4. This revision was agreed by the BPC members.

The BPC also discussed the need to include the aggregated environmental exposure from different product types. The BPC acknowledged that there might be overlap of emissions across product types. However it was concluded that an assessment wa not necessary at the present time due to the lack of appropriate guidance and the fact that the approval of 2-phenoxyethanol for other product types is still pending.

The Commission asked the applicant about the status of the confirmatory data to be provided 6 months before the approval of the active substance and reminded MSCAs and the applicant that this type data should have been provided well in advance in order to be included in the BPC opinion.

The rest of open issues on the assessment report (AR) and the opinion were afterwards discussed and the modifications are described in the open issues table.

It was clarified that, although the opinion can be adopted, the eCA will have to conclude on the ED assessment according to the new scientific criteria before the Standing Committee on biocidal products can be consulted on a decision. The eCA should therefore start such work without delay.

The Assessment Report and the BPC Opinions were adopted by the BPC by consensus, subject to the changes agreed during the meeting.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the BPC Secretariat by **20 April 2018.**
- **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 **28 March 2018** and publish it on the ECHA website.

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

7.4.1. Transfluthrin for PT 18

The revised Assessment Report including an amended List of Endpoints containing the data submitted after active substance approval was agreed by the BPC.

Actions:

- **Member (NL):** to forward the revised assessment report to the SECR by **20 April 2018**.

7.4.2. Bacillus thuringiensis subsp. Kurstaki for PT 18 and for copper thiocyanate, dicopper oxide and copper flakes (coated with aliphatic acid) for PT 21

The member from FR informed the meeting about the data received after the approval of these active substances and about their conclusions. It was decided that the SECR will inform the members in writing about these conclusions as these are relevant for on-going applications for product authorisation.

The Commission stressed the importance to avoid leaving points not closed during the BPC review (i.e. requirements in section 2.5 of BPC opinions), a need which is illustrated by the present cases.

Actions:

- **SECR:** to inform the members in writing on the conclusions of FR with respect to the evaluation of these post approval data.

7.5 Assessment of endocrine disrupting properties in active substance approval

SECR presented the document, proposing a principle that the evaluating CAs should consult the Endocrine Disruptor Expert Group (ED EG) in all cases except if they conclude there to be sufficient information to make a conclusion regarding the ED properties of the active substance. This approach was supported by the members, as it was considered important to avoid as much as possible situations where the ED EG would have to be consulted during the peer review without an added value.

It was clarified that no specific format is required and the CAR template can be used in providing the information to the ED EG, including as much information on the possible ED properties as possible.

The nature of the advice received from the ED EG was discussed. It should be regarded as scientific advice rather than providing a definitive regulatory conclusion but would normally expected to be followed, as it may not be conclusive and it is not a regulatory conclusion but should be regarded as scientific advice. However, if the the advice by the eCA and the BPC, is disregarded or there are diverging views in the ED EG, this should be

reflected in the CAR. The conclusions on whether an active substance meets the ED criteria (Section A or Section B) are made by the BPC Working Groups, and the conclusion on meeting the exclusion or substitution criteria are made by the BPC.

The legal basis of requesting further vertebrate studies was discussed. It was considered that such information can be requested because the BPR requires a conclusion to be made on ED properties and the criteria will be applicable in June 2018. Furthermore, this is reflected in the two CA meeting documents on the implementation of ED criteria. This also concerns co-formulants in biocidal products. The evaluating CA may request further information, and the applicant will have to verify whether the requested study has already been performed. However, such studies regarding ED properties will however rarely be already available for biocide active substances.

The Chairman informed that the document will be revised following the BPC discussion and the discussion at the CA meeting, where two documents on the implementation of the ED criteria are being discussed. A commenting period was also announced to be opened in S-CIRCABC. A revised document will be provided for BPC-25.

Actions:

- **SECR:** to open a Newsgroup on the BPC CIRCABC IG.
- **Members:** To provide comments by **28 March 2018.**
- **SECR:** to revise the document after the agreement of the Commission note and prepare a revised version for the next BPC.

8. Union authorisation

8.1 Update on Union authorisation

An update on Union authorisation was given by the SECR to present: an overview of the current status of the applications in the ECHA's pipeline; an outline of the ongoing activities; and the planning for the discussions at the upcoming Working Group and BPC meetings.

SECR indicated that further discussion is needed on the applicability of the "fast-track approach". One comment was received after the commenting period and will be taken into account when making the draft proposal, which is foreseen to be presented at the BPC-25 meeting. It was also remarked that the peer-review of Union authorisation applications should not include a detailed assessment of the dossier by all the Member States, but should be performed in line with the spirit of the mutual recognition process.

Actions:

- **SECR**: to upload the presentation to S-CIRCABC.
- **SECR**: to prepare a proposal for the next BPC meeting on the "fast-track procedure".

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

A BPC opinion on a Union authorisation application for a product family containing iodine PVP-iodine was adopted by consensus. The BPC considered that, when the products belonging to the product family are used according to the conditions as stated in the Summary of Product Characteristics (SPC), the products will be efficacious and will not by themselves present an unacceptable risk to human and animal health nor the environment.

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 18 March 2018.
- **SECR**: to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR**: to forward the adopted opinion, draft SPC and PAR to COM by 19 March 2018.
- **SECR**: to forward the translated draft SPC to COM by 19 April 2018.

8.3 Iodate in biocidal products containing iodine / PVP-iodine as active substance: TAB entry

The Chairman presented the revised version of the TAB entry. General support was given to the document. However, it was proposed to remove the last paragraph before the "Conclusion" section and to rephrase the sentence before this paragraph. The Chairman indicated that the Coordination Group meeting would be informed of the revised TAB entry, as it is relevant for Union as well as national authorisation applications.

Actions:

- **SECR:** to revise the document and publish it in the TAB and in the BPC CIRCABC IG. ECHA to inform the CG meeting.

9. Dermal absorption

9.1 Guidance document on dermal absorption

SECR had provided the meeting document which, if agreed by the BPC, would replace the document *CA-July13-Doc.6.2.b – Final*. The document proposed to apply the EFSA *Guidance on dermal absorption* (2017) to biocides. The members largely supported the document, noting the importance of providing further guidance as the EFSA guidance is not fully applicable to all biocidal products and product types.

The main purpose of the document was to endorse the EFSA guidance, recognising that there is the need to provide further specific guidance. Such development of further guidance should take into account all the existing guidance, including the current TAB entries.

The applicability dates of the guidance was discussed, as some members preferred to start using the new guidance immediately. The BPC concluded that it is appropriate to follow the existing guidance on applicability of the guidance for products (*CA-July12-Doc.6.2d – Final*) and active substances (*Applicability time of new guidance and guidance-related documents in active substance approval*, agreed at BPC-13).

The following additional text was proposed by SECR and supported by the members: "*The applicability date of the EFSA Guidance on dermal absorption (2017) should be determined according to the rules set for the applicability of guidance for biocidal products*[1] *and biocidal active substances*[2]*. As the basis for establishing the specific applicability timelines, the date of endorsement of this document at the BPC should be used.*"

The BPC agreed on the document without further changes.

Actions:

- **SECR:** to finalise the document and to inform the Human Health WG.

10. Assessment of relevant impurities

10.1 ECHA proposal for timelines on preparing guidance on the assessment of relevant impurities

SECR introduced the document, suggesting the process and a timeline for agreeing on the definition of relevant impurities and the relation of reference specification and the batches used in eco(toxicity) testing. The lack of an interim approach was regretted but it was also considered that the current practices should be continued with sufficient flexibility to ensure that substances are not held up due to not having an agreement on the general principles.

The members supported the process and timeline proposed by SECR.

Actions:

- **SECR:** to provide a proposal on both questions in May 2018 and open a Newsgroup for commenting.

[1] CA-July12-Doc.6.2d – Final

[2] *Applicability time of new guidance and guidance-related documents in active substance approval*; available at https://echa.europa.eu/documents/10162/4221979/applicability_guidance_jan_16_en.pdf

11. Treated articles

11.1 Risk assessment for treated articles / materials at active substance approval stage and the consequences for risk mitigation

The Chairman introduced the discussion item and explained the background: As a follow-up to the WG-V-2017 discussion on silver copper zeolite (PTs 2,4,7,9), the applicants submitted new migration data in order to clarify the migration of copper from silver copper zeolitei.e., the data has been neither seen nor discussed by the Working Group Human Health. The dataset revealed migration rates of silver from treated textiles to saliva and sweat that was significantly higher as compared to the migration data applied for the Human Health risk assessment. SE, the eCA, had submitted a discussion paper 'Migration of active substance from treated polymers and textiles – possible ways forward for risk mitigation and approval decision.' with three questions to be discussed by the BPC. The applicant submitted a position paper reacting a.o. to these three questions.

Q1 Are all migration data relevant for the risk assessment of the active substance?

The eCA pointed at seemingly contradicting information by the applicant on the incorporation of the active substance in articles. One member reminded that the BPC was not the correct forum to discuss technical/scientific data. The member furthermore drew a comparison to complex PT8 discussions in the past because of inconsistent leaching rates, data which depends on the active substances' intrinsic properties, the nature of the treated material, the actual treatment process etc., i.e. factors that may well result in inconsistent leaching/migration rates. The member furthermore pointed at previous Working Group discussions on leaching assessment for PT9 and asked the eCA to use all available sources for a weight of evidence approach. COM referred to past cases on PT 8 and 21, pointing at the importance of considering the assessment methodology independently on the active substances to ensure consistency in evaluations, and asked the eCA to carefully consider the method, the use of data and safety factors, also in comparison to similar previous cases or other on-going other eCAs for other active substances. One member emphasised the need for harmonisation and the need for a fair treatment of the applicant. The eCA pointed out that the way different applicants chose to describe the use(s) in treated articles leads to inconsistencies in the treatment of applicants, since only those uses described in the dossier are assessed. Some applicants describe a very narrow use (one very specific type of treated article used under specific condition), whereas in the actual case the applicant provided a very broad description of areas of use (a large number of different treated articles used under variable conditions) . The Chairman pointed at the lack of similar cases which might require new approaches and pointed at the risk of delaying the overall approval process. The eCA agreed and confirmed that the total dataset on migration to sweat and saliva from treated textiles is currently based on two samples.

The Chairman emphasised the unique character of the situation. COM suggested an overview of all on-going approval cases on substances with similar textile application and the respective representative use for PT9 cases, in order to assure consistency for the assessment. The eCA confirmed that there are no previous examples available of comparable application in treated textiles. The eCA proposed a re-calculation in a separate document, to allow for a comparison of the current CAR calculations and the new one and to allow for the applicant to shed light on the materials used. A member informed the BPC on their experience with a case of textile treated with propiconazole (PT9). Another

member asked for a technical evaluation on the available data by the Working Group instead of directly applying a worst case approach.

The eCA summarised that it had identified use categories that show unacceptable risk and which therefore require a decision. The eCA pointed at the possible major but currently unknown amounts of imported treated articles. The eCA proposed that the following risk mitigation measure may be an option to consider: (a) specific migration limits, or (b) to identify risky uses and apply conditions also for imported treated articles, or (c) labelling requirements (as done for propiconazole), and asked for further suggestions. The Chairman pointed at the CA guidance on treated articles that lists, among others, conditions for restrictions.

Q2 How can it be ensured that only such articles are placed on the market that comply with the uses assessed in the risk assessment and that show acceptable risk?

Q3 Should the substance not be approved if the options described in question 2 are not possible or meaningful?

There were no reactions to Q2 and 3. COM informed the meeting that discussions and agreements already took place in 2014-2015 at policy level in the CA meeting on the cases where specific measures would be relevant in the approvals as regards to treated articles : it was agreed that it is possible to impose Risk Management Measures (RMM) at approval stage under the condition of a major concern linked to a critical effect and informed that so far RMM had been applied for a limited number of specific cases only. As regards to the nature of the risk mitigation measure, this should be a case-by-case decision depending on the nature of the major concern, as well as the feasibility of the risk mitigation measure.

The Chairman suggested a Newsgroup for commenting on the submitted documents.

Actions:

- **SECR:** to open a Newsgroup on the BPC CIRCABC IG.
- **Members:** To provide comments by **20 March 2018**.

12. Any other business

12.1 Harmonised List of Endpoints for pyrethroid metabolites

SECR presented the document on the harmonisation of the environmental assessment for pyrethroid metabolites. General support was given to the proposal and it was agreed to create the harmonised list of endpoints for the pyrethroid metabolites. It was discussed that involvement of the Coordination Grouop (CG) is not necessary but the CG should be actively informed about the progress of the project.

Actions:

- **SECR:** to carry out the necessary preparatory work and to inform the eCAs on the next steps of the project. ECHA to inform the CG meeting.

13. 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 24th meeting of BPC

6-7 March 2018

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-23	
The revised version of the minutes of BPC-23 was agreed as proposed subject to several editorial modifications. SECR informed the meeting about the implementation of the criteria for endocrine-disrupting properties (Regulation (EU) 2017/2100) in the active substance approval process.	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website. **SECR:** to make the presentation on the implementation of the criteria for endocrine-disrupting properties available via CIRCA BC.
Item 5 – Administrative issues	
5.3 Mandate of the Ad-hoc Working Group Environmental Exposure	
The BPC agreed on the revised mandate for the Ad-hoc Working Group Environmental Exposure.	
Item 6 - Work programme for BPC	
6.1 Revised Work Programme 2018-2019 **6.2 Outlook for BPC**	
	Members: to send information on any further changes to the Work Programme (WP) to the SECR by **16 March 2018.** **SECR:** on the basis of the changes to update the WP on the ECHA website and in the BPC CIRCABC IG.
6.3 New requests from the Commission related to Article 38 and Article 75(1)(g)	
The BPC was informed about two requests from the Commission related to Article 38 and 75(1)(g). It was agreed that ECHA will act as the rapporteur for the Article 75(1)(g) request.	
Item 7 - Applications for approval of active substances	
7.1 Working procedure for active substance approval	
The revised working procedure was agreed.	**SECR:** will finalise, taking into account the comments made at the meeting, and will publish

	the working procedure on the ECHA website and on BPC CIRCABC IG. **SECR:** to consult with COM on whether the assessment of Article 5(2) needs to be included in the draft evaluation submitted by the eCA for peer review.
7.2 Draft BPC opinion on salicylic acid for PT 2, 3 and 4	
The BPC adopted by consensus the opinions for the approval of the active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **20 April 2018.** **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 **28 March 2018** and publish it on the ECHA website.
7.3 Draft BPC opinion on 2-Phenoxyethanol for PT 1, 2 and 4	
The BPC adopted by consensus the opinions for the approval of the active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **20 April 2018**. **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 **28 March 2018** and publish it on the ECHA website.
7.4 Revised Assessment Report following the submission of data after active substance approval:	
7.4.1 Transfluthrin - PT 18	
The BPC agreed on the revised List of Endpoints.	**Member (NL)**: to forward the revised assessment report to the SECR by **20 April 2018**.
7.4.2 Bacillus thuringiensis subsp. Kurstaki - PT 18 and for copper thiocyanate, dicopper oxide and copper flakes (coated with aliphatic acid) for PT 21	
The member from FR informed the BPC about the data submitted after the approval of these active substances.	**SECR:** to inform the members in writing on the conclusions of FR with respect to the evaluation of these post approval data.
7.5 Assessment of endocrine disrupting properties in active substance approval	
The BPC discussed the document which was presented at the meeting. The document will be updated once the Commission note on "Implementation of scientific criteria to determine the endocrine-disrupting properties of active	**SECR:** to open a Newsgroup on the BPC CIRCABC IG. **Members**: To provide comments by **28 March 2018.**

substances currently under assessment" is agreed at the CA meeting.	**SECR:** to revise the document after the agreement of the Commission note and prepare a revised version for the next BPC.
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 BPC CIRCABC IG. **SECR**: to prepare a proposal for the next BPC meeting on the "fast-track procedure".
8.2 Draft BPC opinions on Union authorisation applications for product families containing iodine / PVP-iodine	
The BPC adopted by consensus the opinion for the authorisation of the 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 **18 March 2018**. **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion, draft SPC and PAR to COM by **19 March 2018**. **SECR**: to forward the translated draft SPC to COM by **19 April 2018**.
8.3 Iodate in biocidal products containing iodine / PVP-iodine as active substance: TAB entry	
The BPC agreed on a revised version of the document which was presented at the meeting.	**SECR:** to revise the document and publish it in the TAB and in the BPC CIRCABC IG. ECHA to inform the CG meeting.
Item 9 – Dermal absorption	
9.1 Guidance document on dermal absorption	
The BPC agreed on the document which was presented at the meeting.	**SECR:** to finalise the document and to inform the Human Health WG.
Item 10 – Assessment of relevant impurities	
10.1. ECHA proposal for timelines on preparing guidance on the assessment of relevant impurities	
The BPC agreed on the document which was presented at the meeting.	
Item 11 – Treated articles	
11.1. Risk assessment for treated articles / materials at active substance approval stage and the consequences for risk mitigation	

	SECR: to open a Newsgroup on the BPC CIRCABC IG. **Members**: To provide comments by **20 March 2018.**
Item 12 – Any other business	
12.1. Harmonised List of Endpoints for pyrethroid metabolites	
The BPC agreed on the proposal listed in the document.	

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Part III - List of Attendees

Members	European Commission
CEBASEK Petra (SI)	CHATELIN Ludovic (DG SANTE)
COSTIGAN Michael (UK)	
DRAGOIU Simona (RO)	**Advisers**
GAVRIEL Alexandros (CY)	GAUSTAD Astrid (NO)
GIORDMAINA Wayne (MT)	GREGERSEN Nina Falk (DK)
GONZALEZ MARQUEZ Maria Luisa (ES)	HUIZING Tjaart-Jan (NL)
HADAM Anna (PL)	VAN DER MEER Cindy (NL)
HAHLBECK Edda (SE)	WEINHEIMER Viola (DE)
JAGER Stefanie (DE)	WELTEN Angelique (NL)
JOHN Nina (AT)	ZIKOVA Andrea (DE)
KOIVISTO Sanna (FI)	
LANS Martine (NL)	**Accredited Stakeholder Observers**
LARSEN Jørgen (DK)	MIHAI Camelia (CEFIC)
MERISTE Anu (EE)	
MIKOLASKOVA Denisa (SK)	**ECHA Staff**
RANDALL Marit (NO)	AIRAKSINEN Antero
RUSCONI Manuel (CH)	ESTEVAN MARTINEZ Carmen
SZANTO Emese (HU)	KURONEN Terhi
VAGIAS Vasileios (EL)	LAITINEN Jaana
VAN BERLO Boris (BE)	MULLER Gesine
VRHOVAC FILIPOVIC Ivana (HR)	PECORINI Chiara
Alternate members	SCHIMMELPFENNIG Heike
CARBERRY Stephen (IE)	VAN DE PLASSCHE Erik
COLLET Romy (FR)	
CRESTI Raffaella (IT)	
ENSCH Svenja (LU)	
MIKOLÃS Jan (CZ)	

Applicants	Apologies
CHAMP Samantha (BASF SE) for 2-Phenoxyethanol for PT 1, 2 and 4	BORGES Teresa (PT)
CLAASSENS Marinus (Salicylic Acid Consortium) for salicylic acid for PT 2, 3 and 4	BROVKINA Julija (LV)
GOODYEAR Andrew (EU BPR Silver Task Force) for Risk assessment for treated articles / materials at active substance approval stage and the consequences for risk mitigation	
HAMANN Matthias (CALVATIS - CVAS Development GmbH) for Union Authorisation: Iodine/PVP-iodine	
Experts accompanying applicants	
BADE Steffen, accompanying CHAMP Samantha, for 2-Phenoxyethanol for PT 1, 2 and 4	
WAGNER Silvia, accompanying HAMANN Matthias, for Union Authorisation: Iodine/PVP-iodine	

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-24

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-24 meeting

Meeting documents		
Agenda Point	**Number**	**Title**
2	BPC-A-24-2018_rev2	Draft agenda
4	BPC-M-23-2017	Draft minutes from BPC-23
5.2	BPC-24-2018-01	Administrative issues and report from the other Committees
5.3	BPC-24-2018-16	Mandate of the Ad-hoc Working Group Environmental Exposure
6.1	BPC-24-2018-02	BPC updated Work Programme 2017-2018
6.2	BPC-24-2018-03	Outlook for the BPC
6.3	BPC-24-2018-17 BPC-24-2018-18	New requests from the Commission related to for Article 38 and Article 75(1)(g)
7.1	BPC-24-2018-04	Working procedure for CARs submitted to ECHA for AS approval failing the accordance check
7.4	BPC-24-2018-11A BPC-24-2018-11B_Rev1 BPC-24-2018-11B_Rev2_Room document	Revised Assessment Report following the submission of data after active substance approval: 7.4.1. Transflutrhin for PT 18
		7.4.2 Bacillus thuringiensis subsp. Kurstaki for PT 18 and for copper thiocyanate, dicopper oxide and copper flakes (coated with aliphatic acid) for PT 21
7.5	BPC-24-2018-19	Assessment of endocrine disrupting properties in active substance approval
8.3	BPC-24-2018-13	Iodate in biocidal products containing iodine / PVP-iodine as active substance: TAB entry
9.1	BPC-24-2018-14	Guidance document on dermal absorption
10.1	BPC-24-2018-15	ECHA proposal for timelines on preparing guidance on the assessment of relevant impurities
11.1	BPC-24-2018-20	Risk assessment for treated articles / materials at active substance approval stage and the consequences for risk mitigation
	BPC-24-2018-22	Position paper from the Task Force
12.1	BPC-24-2018-21	Harmonised List of Endpoints for pyrethroid metabolites

Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.2	BPC-24-2018-05A	Salicylic acid PT 2	Draft BPC opinion
	BPC-24-2018-05B		Assessment report
	BPC-24-2018-05C		Open issues
	BPC-24-2018-06A	Salicylic acid PT 3	Draft BPC opinion
	BPC-24-2018-06B		Assessment report
	BPC-24-2018-06C		Open issues
	BPC-24-2018-07A	Salicylic acid PT 4	Draft BPC opinion
	BPC-24-2018-07B		Assessment report
	BPC-24-2018-07C		Open issues
7.3	BPC-24-2018-08A	2-Phenoxyethanol PT 1	Draft BPC opinion
	BPC-24-2018-08B		Assessment report
	BPC-24-2018-08C		Open issues
	BPC-24-2018-09A	2-Phenoxyethanol PT 2	Draft BPC opinion
	BPC-24-2018-08B		Assessment report
	BPC-24-2018-08C		Open issues
	BPC-24-2018-23_Room document		Clarification of Secondary Exposure Scenarios in PT's 2 and 4
	BPC-24-2018-10A	2-Phenoxyethanol PT 4	Draft BPC opinion
	BPC-24-2018-08B		Assessment report
	BPC-24-2018-08C		Open issues
	BPC-24-2018-23_Room document		Clarification of Secondary Exposure Scenarios in PT's 2 and 4
8.2	BPC-24-2018-12A	UA: product families containing iodine / PVP-iodine	Draft BPC opinion
	BPC-24-2018-12B		SPC
	BPC-24-2018-12C		PAR
	BPC-24-2018-12C1		Confid. Annex 1 to PAR
	BPC-24-2018-12C2		Annex 2 to PAR
	BPC-24-2018-12C3		Confid. Annex 3 to PAR
	BPC-24-2018-12D		Open issues

23 February 2018
BPC-A-24-2018_rev2

Draft agenda

24th meeting of the Biocidal Products Committee (BPC)

6 – 7 March 2018

ECHA Conference Centre, Annankatu 18, Helsinki

Starts on 6 March at 09:30, ends on 7 March at 13:00

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-24-2018

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-23

BPC-M-23-2017

For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

BPC-24-2018-01

For information

5.3. Mandate of the Ad-hoc Working Group Environmental Exposure

BPC-24-2018-16

For agreement

6. – Work programme for BPC

6.1. Revised BPC Work Programme 2018-2019

BPC-24-2018-02

For information

6.2. Outlook for BPC

BPC-24-2018-03

For information

6.3. New requests from the Commission related to Article 38 and Article 75(1)(g)

BPC-24-2018-17

BPC-24-2018-18

For information and agreement

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

7.1. Working procedure for active substance approval

BPC-24-2018-04

For agreement

7.2. Draft BPC opinion on salicylic acid for PT 2, 3, 4

Previous discussion(s): WG-V-2017

PT2: BPC-24-2018-05A, B, C

PT3: BPC-24-2018-06A, B, C

PT4: BPC-24-2018-07A, B, C

For adoption

7.3. Draft BPC opinion on 2-Phenoxyethanol for PT 1, 2, 4

Previous discussion(s): WG-IV-2017

PT1: BPC-24-2018-08A, B, C

PT2: BPC-24-2018-09A, B, C

PT4: BPC-24-2018-10A, B, C

For adoption

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

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

7.4.1. Transflutrhin for PT 18

BPC-24-2018-11A, B

For agreement

7.4.2. Bacillus thuringiensis subsp. Kurstaki for PT 18 and for copper thiocyanate, dicopper oxide and copper flakes (coated with aliphatic acid) for PT 21

For information

7.5. Assessment of endocrine disrupting properties in active substance approval

BPC-24-2018-19

For discussion and agreement

Item 8 – Union authorisation[§]

8.1 Update on Union authorisation

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

BPC-24-2018-12A, B, C and D

For adoption

8.3 Iodate in biocidal products containing iodine / PVP-iodine as active substance: TAB entry

BPC-24-2018-13

For agreement

Item 9 – Dermal absorption

9.1 Guidance document on dermal absorption

BPC-24-2018-14

For agreement

[§] 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).

Item 10 – Assessment of relevant impurities

10.1 ECHA proposal for timelines on preparing guidance on the assessment of relevant impurities

BPC-24-2018-15

For discussion and agreement

Item 11 – Treated articles

11.1 Risk assessment for treated articles / materials at active substance approval stage and the consequences for risk mitigation

BPC-24-2018-20

For discussion

Item 12 – Any other business

12.1 Harmonised List of Endpoints for pyrethroid metabolites

BPC-24-2018-21

For information

Item 13 – Action points and conclusions

For agreement

Provisional time schedule for the

24th meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Annankatu 18, Helsinki

6 March 2018: starts at 09:30; 7 March ends at 13:00

Please note that the time schedule indicated below are 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.

Tueday 6 March: morning session

Items 1-5	Opening items and administrative issues
Item 6	Work programme of the BPC 2018-19
Item 7.2	Draft BPC opinion on salicylic acid for PT 2, 3, 4

Tuesday 6 March: afternoon session

Item 7.3	Draft BPC opinion on 2-Phenoxyethanol for PT 1, 2, 4
Item 7.4	Revised Assessment Report following the submission of data after active substance approval:
	7.4.1. Transflutrhin for PT 18
	7.4.2 Bacillus thuringiensis subsp. Kurstaki for PT 18 and for copper thiocyanate, dicopper oxide and copper flakes (coated with aliphatic acid) for PT 21
Item 7.1	Working procedure for active substance approval
Item 7.5	Assessment of endocrine disrupting properties in active substance approval
Item 9.1	Guidance document on dermal absorption
Item 10.1	ECHA proposal for timelines on preparing guidance on the assessment of relevant impurities

Wednesday 7 March: morning session

Item 8.1	Update on Union authorisation
Item 8.2	Draft BPC opinion on Union authorisation application for product families containing iodine / PVP-iodine
Item 8.3	Iodate in biocidal products containing iodine / PVP-iodine as active substance: TAB entry
Item 11.1	Risk assessment for treated articles / materials at active substance approval stage and the consequences for risk mitigation
Item 12	AOB:
	12.1: Harmonised List of Endpoints for pyrethroid metabolites
Item 13	Action points and conclusions

End of meeting

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