11 December 2018

BPC-M-27-2018

Minutes of the 27th meeting of the Biocidal Products Committee (BPC)

16-18 October 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 27th BPC meeting.

Regarding the BPC membership, the Chairman stated that there are no changes, except that the nomination of an alternate member for Malta is pending.

The Chairman then informed the BPC members of the participation of 28 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 attended the meeting.

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-27-2018_rev1) and invited any additional items. No items were added.

The Chairman indicated that the agenda item 7.1.3 on the “Presentation of the PBT status in the BPC opinion” was removed and will be discussed at the next meeting.

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-26

The revised draft minutes from BPC-26 (BPC-M-26-2018), incorporating the comments received, were agreed.

The Chairman noted that the actions from BPC-26 have been carried out.

The Chairman informed the meeting on the question on the use of IUCLID in the CLH process: IUCLID cannot be used for a CLH dossier due to the public consultation process (not possible to distribute IUCLID files). This is the reason why ECHA has made a tool to convert IUCLID to the appropriate format in Word for the CLH dossier. An improved version of this tool will soon be available.

The Chairman informed the meeting on the use of the combined BPR – CLH template.

The Chairman informed the meeting about the results of the interviews with all the BPC members.

Actions:

- **SECR:** to upload the agreed minutes from BPC-26 to the BPC CIRCABC IG and to the ECHA website after the meeting.

5. Administrative issues

5.1 Housekeeping issues

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

5.2 Administrative updates and report from other ECHA bodies

The Chairman introduced document BPC-27-2018-01 prepared by ECHA for the Management Board meeting which contains the progress reports for each Committee including the PBT and ED Expert Groups.

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 2 November 2018 after which an updated version will be published on the ECHA website.

The Chairman stated that:

- For active substance approval the number of opinions adopted this year is 19. It is unclear currently what the number will be considering that for several active substances scheduled for this and the next BPC the ED assessment is not finalised but certainly the number of 50 will not be reached. The Chairman stated that the

work programme for 2019 is highly uncertain due to the same reason. Lastly the Chairman expressed his concern that more than 70 active substance PT combinations (PT 1 and 2) of the third priority list are under evaluation where according to Regulation (EU) 492/2014 the eCA has to submit the draft CAR to ECHA by 31 December 2018.

- For Union authorisation the number of scheduled opinions for 2018 is still 4. For 2019 several scheduled opinions have been postponed comparing the outlook of last with this meeting. The Chairman referred to agenda item 8.1 for a further discussion.

The Chairman furthermore stated that:

- One draft CAR was submitted for the last process flow which ended 28 September. Considering the low numbers, meetings in 2019 may be cancelled pending discussions on backlog dossiers or Union authorisations.
- The Chairman asked the eCAs with active substances scheduled for discussion at the December BPC meeting (BPC-28) to confirm this planning to the SECR by 31 October 2018.

The SECR informed the meeting of a workshop on the improvement of the active substance approval process, to take place on 12 - 13 February 2019. BPC members were informed that they would soon receive an invitation to participate in the organisation of the workshop and to nominate participants to the workshop itself.

The SECR presented a short progress report on the Grip on the Review Programme project. All member states have provided an overview of the ongoing dossiers in the review programme. Some member states will be contacted for further clarifications.

Preliminary results indicate that many dossiers are stuck due to applicants needing to provide additional information. ED criteria are also a major issue due to additional information required or MSs struggling with performing the assessment. Several MSs further reported that they didn’t have sufficient resources.

Future actions by ECHA as a response to the outcome of the project is to provide information on how to cope with ED criteria, inform on what actions can be taken to force applicants to deliver information in time, coordinate in situ dossiers as has been done already, provide support on individual dossiers.

By providing more knowledge on the process to the member states and by strengthening the relations between member states and ECHA, ECHA aims to improve the progress of the review programme and other processes.

ECHA further stressed that member states should always feel free to contact ECHA on issues they need help on.

Several questions were raised by the members.

ECHA confirmed that the outcome of the project will be presented with specific details on the role of industry and MSCAs in the delays. It would be possible to add an agenda item to future BPC meetings to address procedural issues.

ECHA explained that multiple people will be allowed per member state to join the workshop, only one representative per member state would be reimbursed. It is to be considered whether the meeting can be followed via Webex, however active participation in person would be preferred.

Similarly to previous meetings, the Commission expressed concerns on the general progress and reminded that Member States must implement the actions agreed at the CA meeting, in particular to deliver the draft assessment reports, and to not postpone discussions on their substances from BPC meetings to BPC meetings. Progress must also be made on backlog reports submitted before 1st September 2013.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) and on the overview of the status on harmonised classification and labelling for active substances to the SECR by **2 November 2018**.
- **SECR**: on the basis of the changes to update the work programme on the ECHA website and in the BPC CIRCABC IG.
- **The relevant eCAs** to confirm to the SECR that their active substances scheduled for discussion at October BPC meeting will remain on track by **31 October 2018**.

6.3 Status harmonised classification and labelling for active substances

The SECR presented an overview on the status of harmonised classification and labelling of active substances which have been approved or are still under review under BPD/BPR. The table presenting the overview will be updated for each BPC. The BPC members were asked to check the information provided.

The Commission reminded members that it is important that Member States make such harmonised classification dossiers as provided under the CLP regulation. This is in particular relevant when active substances meet the exclusion or substitution criteria due to their classification.

Actions:

- **Members**: to send information on the overview of the status on harmonised classification and labelling for active substances to the SECR by **2 November 2018**.
- **SECR**: to provide an update the status of harmonised classification and labelling for active substances for the next BPC meeting; and to provide a similar overview for PBT and ED assessments for active substances.
- **SECR**: to upload the presentation on CLH on the BPC CIRCABC IG

7. Applications for approval of active substances

7.1. Procedural and administrative aspects:

7.1.1. Template BPC opinion for active substance approval

The SECR reported that the table under section 2.2.1 in the opinion template has been modified due to the introduction of the ED criteria. The text '*Intended mode of action that consists of controlling target organisms via their endocrine system(s)*' will be changed into '*Intended mode of action that consists of controlling non-vertebrate target organisms via their endocrine system(s)*' as requested by the BPC members.

Additionally, it was informed that the SECR plans to change the title in section 2.2.3. in order not to limit it to information received via public consultation. COM welcomed the change and encouraged the BPC members to provide their own expertise in regard of identifying possible alternatives for candidates for substitution.

Actions:

- **SECR:** to provide a revised template for the next BPC.

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

The members of the committee were asked to check the standard conditions presented in the document when an opinion is prepared. The Chairman stated that there have been no changes introduced in the document.

Actions:

- **Members:** To check the standard conditions when preparing opinions.

7.2 - 7.5 Draft BPC opinion on silver zinc zeolite, silver zeolite, silver copper zeolite and silver sodium hydrogen zirconium phosphate for PT 2, 4, 7 and 9

The Chairman welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The rapporteur presented the current status of the applications.

The Chairman introduced the agenda items by stating that: i) the intention is to adopt the draft opinions for silver zeolite (SZ), silver copper zeolite (SCZ) and silver sodium hydrogen zirconium phosphate (SSHZP) for PT 2 and 7 at the meeting; ii) have a first discussion on silver zinc zeolite (SZZ), silver copper zeolite and silver sodium hydrogen zirconium phosphate for PT 4 focussing on the dietary risk assessment; iii) have a first discussion on SZZ for PT 2, 7 and 9 and on SZ, SCZ and SSHZP for PT 9 focussing on the proposals from the rapporteur on restrictions for treated articles.

The rapporteur clarified that the assessment of the endocrine disrupter properties was on-going and could not be finalised based on the data currently available. The Chairman

stated that conclusions are required for both human health and environment (section A and B of the annex of Regulation (EU) 2017/2100), but that an opinion containing a non-approval proposal can be adopted in line with the available guidance note from the CA meeting.

The applicant presented their position paper including an overview of their main comments."

Silver zeolite, silver copper zeolite and silver sodium hydrogen zirconium phosphate for PT 2 and 7

The main comments in the open issue tables related to the draft Assessment Report and draft opinions were discussed.

The rapporteur explained that the silver core dossier is a document that can be further used for future evaluations of other silver containing active substances. One member pointed at the need to alter the core dossier in case there are new relevant data. The rapporteur agreed to be flexible and change the list of endpoints (LoEP) if needed. The applicant pointed at the rather static nature of the core dossier and that endpoints would probably not change significantly as a consequence of other applications.

Several members raised the issue of the terminology used in the assessment of human exposure from the use of treated articles, and that the exact representative uses supported by the applicant were not clear. The rapporteur explained that the applicant has not been fully clear on the claims made and the uses defended and explained the approach followed – among others the distinction between different categories based on exposed area and exposure duration - and the selection of example uses for which the assessment was made. It was decided to describe the approach in detail in the Assessment Report while describing only the principles in the opinions. In addition, it was decided to remove the examples from the opinions.

Several members required to describe the scenarios leading to unacceptable as well as acceptable risks in the opinions in the overall conclusions. This was agreed upon. In addition, the rapporteur will align as much as possible the uses assessed in terms of efficacy with the uses assessed for the risks to human health and environment and between the latter two, and how these are reflected and summarised in the BPC opinions.

Several members asked to streamline the sections on "effectiveness" in the opinions, which was agreed upon. The applicant stated they initially submitted a 'diverse set of uses' with the intention to refine it to one single description in the context of a very broad description why and how these substances are being used. The claim would be antifungal and antibacterial within the context of the overall use of the treated material: the intention is treating the article to provide a reduction in fungal or bacteria growth on a surface, which results then in increased bacterial and fungal protection for the material or protection of the user (by comparing such a treated surface to an untreated surface).

The applicant stated that they were not required to demonstrate innate activity as usually made at the approval stage, but were required to show the benefit of the treatment which they consider a change of policy. The rapporteur disagreed with the use of the term 'benefit', as no assessment of the benefit of having such treated article on the market was made (ie. benefit for the user, for society or the market of having such treated articles etc.), but that sufficient efficacy needs to be demonstrated for the active substances at

the approval stage. The rapporteur pointed to the vague use descriptions in the applications and stated that a clear definition of use conditions was key. The rapporteur furthermore underlined that humid conditions represented a crucial requirement for both silver release and for bacterial growth and that tests conducted by the applicant under non-humid conditions resulted in insufficient growth. The applicant claimed that to require to demonstrate the benefits would be a policy change, and that data that was showing efficacy in the samples treated had been rejected on the basis of the lack of growth in the controls. whereas according to the applicant, *"controls means that you need to show a benefit for what is claimed at the active substance approval level, that is a change in policy and we cannot qualify this differently*". The SECR disagreed that there was a change in policy and referred to the fact that innate activity needs to be proven at approval stage and that clarity on the claims was needed. The applicant claimed new guidance was applied retrospectively in the Working Group on Efficacy (WG EFF) referring to a note distributed by the Commission in September 2015. The SECR – referring to an overview prepared for the WG EFF – stated the 'transitional guidance for disinfectants and preservatives' was applied correctly in line with the available guidance agreed by the BPC. SECR further clarified that the appropriate level of demonstration of efficacy was requested at the approval stage on these substances and that further efficacy testing can be requested at the biocidal product authorisation stage after the approval of the active substance. The eCA further indicated that the opportunity has been given to the applicant to provide further efficacy data, which has been even accepted at the very late stage, and that the outcome of the evaluation results from the data provided by the applicant itself. The members agreed with the conclusions on efficacy – ie. that innate efficacy was not demonstrated for PT2 and 7 for these substances – as decribed in the draft opinions: these conclusions adequately reflect the outcome of the WG EFF. The applicant disagreed stating that alternative approaches were suggested (referring to the concept of primary biocidal function) which were more proportional.

The need to incorporate late submission of data on dermal absorption was discussed. The rapporteur stated that preliminary results were submitted in a late stage of the peer review process (, even 5 years after the first discussion in the Technical Meetings for silver zinc zeolite) and a report was submitted after the peer review was finalised. The study, and was neither requested by the eCA nor by the Working Group for Human Health. The SECR explained the assessment was performed assuming a dermal absorption value of 5%. The applicant stated the data should be taken into account as the information is reasonable available to the rapporteur and because it has a significant impact on the outcome of the evaluation. Several members agreed with the rapporteur that it is too late to consider this information. It was concluded that the dermal adsorption study report does not need to be considered and that this conclusion is in line with the available BPC procedural guidance.

Other open issues were discussed and agreed upon by the meeting. The Assessment Report was agreed and the BPC opinions adopted by the meeting by consensus, subject to changes agreed at the meeting.

Silver zinc zeolite, silver copper zeolite, silver zeolite and silver sodium hydrogen zirconium phosphate for PT 4

The Chairman informed the meeting that ECHA was requested by the Commission to consult with EFSA on the outcome of the human health risk assessment and wait with the adoption of the BPC opinions until this consultation has taken place. The request is due to the interplay between the Biocidal Products Regulation and the regulation on Food Contact Materials (EU) No 1935/2004. The Chairman informed that consultations are on-going between ECHA, the Commission and EFSA on the content and time schedule of the consultation.

The rapporteur and SECR provided - following questions by several members - clarifications on the dietary risk assessment performed for two scenarios: i) migration from treated polymers into food (for example a cutting board) from tests performed with food simulants; ii) migration into drinking water from treated water filters. Risks were identified in both scenarios; for the second scenario only for infants. For the first scenario it was clarified that the exposure assessment was performed in line with the methodology applied under Regulation (EU) No 1935/2004 and that specific migration limits (SML) were considered but that these were not compliant with the Acceptable Daily Intake (ADI) derived in the current CARs. The applicant stated their concerns on the exposure and effects assessment which in their view is overconservative. The Chairman highlighted the need for the BPC to get insight into the uncertainties of the assessment or rather the robustness of the assessment outcome.

One member asked to consider the possibility for imposing restrictions of the use in water filters for certain age groups. The practical challenges related to enforcement regarding age limits were discussed. The members were asked to follow-up discussions in their respective MSCAs on how realistic and feasible this risk management measure is. Some members stated there may be a “major concern” (as indicated in the “Note on the specific conditions to be set in the approval of active substances in relation with treated articles” CA-Nov14-Doc.6.2-Final) due to the classification (proposal) as Repr. Cat. 2 and due to a risk indentified for vulnerable groups.

Silver zinc zeolite for PT 2, 7 and 9 and on silver copper zeolite and silver sodium hydrogen zirconium phosphate for PT 9

The rapporteur introduced the proposed restrictions on the use of these active substances in treated articles (plastics and textiles). The Commission reminded the BPC of the CA meeting note (CA-Nov14-Doc.6.2-Final) and asked the BPC to consider various elements for the determination of the existence of a “major concern”: not only the risk quotient, but also the nature of the critical effect(s), the question of proportionality, alternative risk management measures, the level of certainty and/or confidence in the results of the evaluation and possible labelling provisions. The Chairman asked the BPC to further discuss the term “major concern” as it is not well defined in the note. The rapporteur proposed that a “major concern” is identified if unacceptable risks are determined in the assessment (risk quotient between exposure and effects being higher than one). Different views were expressed by several members, where aspects like the feasibility of enforcement, vulnerable groups and the fact that the majority of treated articles is imported into the EU (without product authorisation taking place under the BPR of the biocidal product with which the article is treated) were mentioned. One member considered that there would be a need for enforcement authorities to gather information on the

market, to be able to in future define categories for treated articles and complement these with exposure scenarios for all active substances used to treat articles. As this will be a substantial exercise, the member proposed to initiate this activity aiming so that the outcome can be used for the renewal stage. The same member stated that as long as risk can be refined and lowered to an acceptable level by appropriate data at product authorisation, a risk quotient above 1 cannot be regarded as "major concern". The applicant stated that in this case there is no "major concern" referring to the opinion adopted for carbendazim for product type 7 and 10: in this opinion, no restrictions on the use of treated articles are included even though this substance is meeting the exclusion criteria and is a candidate for substitution. The SECR suggested to the BPC members to discuss the mentioned points regarding "major concern" in their respective MSCAs for the next discussion.

One member proposed to rephrase current proposals like for example "a*ntimicrobial claims not to be* made" to "*antimicrobial claims* was *not demonstrated"* since the submitted studies were not valid and therefore additional studies may demonstrate efficacy at product authorisation. The rapporteur disagreed, pointing at a likely absence of product authorisation in this case. One member and the applicant referred to the BPR which states that any claim on treated articles needs to be substantiated, and consider that issues are addressed by enforcement activities of Member States controlling claims on treated articles and applying the relevant provisions of the Directive on Unfair Commercial Practices 2005/29/EC.

Actions for silver zinc zeolite for PT 2, 4, 7 and 9 and for silver copper zeolite, silver zeolite and silver sodium hydrogen zirconium phosphate for PT 4 and 9:

- **SECR:** to schedule the second discussion on these opinions in consultation with the rapporteur.

Actions on silver zeolite, silver copper zeolite and silver sodium hydrogen zirconium phosphate for PT 2 and 7:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **30 November 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 **9 November 2018** and publish it on the ECHA website.
- **SECR:** to schedule the second discussion on the opinions on silver zeolite for PT 4 and 9 in consultation with the rapporteur.

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

7.6.1. Formaldehyde for PT 3

The evaluating CA Germany informed the meeting that they accepted the post approval data submitted by the applicant. This was agreed by the meeting.

Actions:

- **Member (DE):** to forward the revised assessment report with the List of Endpoints to the SECR by **30 November 2018**.

7.6.2. Margosa extract, cold-pressed oil of Azadirachta indica seeds without shells extracted with super-critical carbon dioxide for PT 19

The evaluating CA Germany informed the meeting that they accepted the post approval data submitted by the applicant. This was agreed by the meeting.

Actions:

- **Member (DE):** to forward the revised assessment report with the List of Endpoints to the SECR by **30 November 2018.**

7.6.3. 2-octyl-isothiazol-3(2H)-one (OIT) for PT 8

The evaluating CA UK informed the meeting that they accepted the post approval data submitted by the applicant. All comments from the commenting MSs have been addressed. This was agreed by the meeting.

Actions:

- **Member (UK):** to forward the revised assessment report with the List of Endpoints to the SECR by **30 November 2018.**

7.6.4. epsilon-Momfluorothrin for PT 18

The evaluating CA UK informed the meeting that they accepted the post approval data submitted by the applicant. This was agreed by the meeting. For the water solubility the values from both studies will be included in the LoEP.

Actions:

- **Member (UK):** to forward the revised assessment report with the List of Endpoints to the SECR by **30 November 2018.**

7.6.5. *Bacillus thuringiensis* subsp. *kurstaki*, serotype 3a3b, strain ABTS-351 for PT 18

The evaluating CA France informed the meeting on the progress on the evaluation of the post approval data. One point remained open related to proposed requirements at product authorisation stage. This was agreed by the meeting.

Actions:

- **Member (FR):** to forward the revised assessment report with the List of Endpoints for the SECR by **30 November 2018**.

7.7 Requesting further information as new test guidelines become available

The SECR presented the updated document after industry and some members commented during the commenting period. The members had been asked to report if similar cases on site-of-contact mutagenicity are available in their home country. Several MSs confirmed that other substances may also be affected. The SECR asked for a discussion on a way forward. It was pointed out by one member that a case-by-case consideration should be avoided. The feasibility of the required test might be questionable and the possibility of a waiving statement was discussed. The SECR asked all members to look into their dossier and inform if more evaluations will be affected.

Actions:

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

7.8 Terminology primary and secondary exposure in the BPC opinion

The revised document by the SECR was agreed by the meeting.

Actions:

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

7.9 Systematic literature review for ED assessment

Performing a systematic literature review is an integral part of the ED criteria. The COM note CA-March18.Doc.7.3.a- Final informs however that, for active substances for which the assessment report is submitted before 1 September 2013, the assessment will be done "*on the basis of information already submitted in the current dossier and/or provided by the applicant*". The intention of the discussion was to clarify the need to perform a systematic literature review for active substances for which the assessment report was submitted before 1 September 2013.

One member reminded that for such substances, the applicant would be given the possibility to provide further information, but there would not be an obligation to provide any. Therefore, as the literature review is part of the ED criteria, it was considered as a task to be performed by the evaluating CA.

The wording of the COM note was discussed, as it seems not to refer only to the information that has to be submitted by the applicant, but it seems to suggest that the assessment is to be done on the basis of the information already submitted. It was reflected that this should not be taken literally as it was intended to refer to the obligations of the applicant and not to limit the information that should be taken into account. It was also mentioned that regardless of the hazard property under assessment, the evaluating CA would in any case be expected to take into account all information readily available, and this would include a literature review. One member clarified that although published literature may be readily available, performing a systematic literature review is a time consuming task where several experts need to be involved.

The Commission pointed out that it was important to follow the agreed ECHA/EFSA guidance document on ED assessment.

The members discussed whether the BPC opinion for these substances could indicate that the necessary data was not submitted and that no conclusion could be drawn on the ED properties. This would be according to the COM note above. One member asked whether it would be possible to limit the extent of the literature review for these substances and assessing their ED properties in detail only at the renewal stage.

Actions:

- **SECR:** to provide a revised document to the next BPC.

8. Union authorisation

8.1 Update on Union authorisation

SECR raised concerns about involvement in pre-submission consultations for union authorisations. The number of responses received is going down and lately hardly any response is received. SECR clarified that every PAR shall contain an assessment of ED criteria. If a PAR is missing any component of the risk assessment, where this nowadays includes an assessment of the ED criteria, the accordance check will fail. SECR informed the members that the process of SPC translations should be adhered to more closely. Especially the deadlines for the steps, informing the applicant about proposed changes and the preparation of form LRUA-F1 were highlighted as points to pay attention to.

The numbers of Union authorisations were presented and the regular coordinating efforts were mentioned. It was mentioned that contact details of the DM are available in R4BP3 and the DM always sends a message with their contact details to inform the eCA. In case of the need for support the DM can be reached either via R4BP messaging or via the provided contact details.

COM mentioned the importance to respect deadlines in order to meet the 3-year deadline after substance approval by which all products should have been authorised under the

BPR. COM further emphasised the need for a good quality of the English version of the SPC, as this has consequences for subsequent translations.

Industry mentioned that MSCAs interpret the way ED properties should be assessed differently, especially with regards to co-formulants. There was some agreement that clarity should be provided on what to do with the co-formulants. In that context the development of a database with information on co-formulants was mentioned.

A request was made to invest in producing a long-term planning of Union authorisations. For this purpose the member states should make sure that reliable information is provided on timelines per individual case.

Actions:

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

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

The Chairman welcomed the applicant for this item. The ASOs were allowed to be present during the discussion. The rapporteur presented the current status of the application.

The discussion focussed on the items included in the open issues table.

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

It was highlighted by another BPC member that the human health risk assessment has been revised compared to the previous iodine Union Authorisation cases. SECR pointed out that certain small deviations in the approach to the risk assessment and the sentences for risk mitigation should be allowed if they serve as improvement for the decision making. Keeping track of these small differences between products with the same active substance/PT combination might be useful. SECR will further reflect upon whether this is needed and report back to the BPC members at the next meeting.

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

The BPC opinion, the PAR and the SPC were adopted by consensus.

Actions:

- **Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **29 October 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 **30 October 2018**.
- **SECR:** to forward the translated draft SPC to COM by **3 December 2018**.

8.3 Working procedure for applications for major change of a Union authorisation

The SECR presented a revised version of the working procedure. In the entire document it is now described that all communication and exchange of documents will run via R4BP3. More time has been created for discussions between MSCAs, this means that there is less time for commenting and trilateral discussions as the overall time for peer review is very limited. A previous request for an accordance check could not be implemented as in that case the process could not be fit in the allocated time.

It should be clarified in the work procedure whether the PAR should be consolidated or whether there should be an addendum as a result of a major change.

COM mentioned that the dossier manager at ECHA could ensure that the English version of the SPC would be of sufficient quality prior to translation into the other languages. This will be further reflected upon at a later stage, the approach should be the same as for the regular applications for union authorisation.

Members agreed on the document as it was presented with the following additions:

Step 3: email notification to BPC member in addition to the creation of the task in R4BP3.

Step 21: it will be clarified whether a consolidated PAR or an addendum to the PAR will be created. It should be brought in line with the agreed approach for national authorisations.

Actions:

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

8.4 Union authorisation major change applications: cooperation during the evaluation stage

SECR was of the opinion that this document did not have to be updated which was agreed by the meeting.

Actions:

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

9. Article 38 opinions

9.1 Draft BPC opinion on "Questions on unresolved objections during mutual recognition of a PT 18 biocidal product family containing 1R-trans phenothrin for use against ants"

The SECR presented an Article 38 draft opinion on several questions requested by the Commission on unresolved objections during the mutual recognition of a PT18 BPF containing 1-R-trans phenotrhin as active substance for use against ants.

The opinion was related to a disagreement on the validity of the efficacy data of the BPF. The SECR explained that a discussion had taken place during the EFF WG-II-2018 meeting, where WG members agreed by majoritiy that, considering the expert judgement applied by the refMS, the efficacy data submitted by the applicant was sufficient to prove the efficacy of the BPF.

During the commenting phase prior to the BPC meeting, the initiating concerned MS commented that, in their opinion, the statistical analysis of the data of the field trial was not acceptable and, therefore, the efficacy study could not be considered as valid. The SECR explained that related to this aspect, the opinion had taken into account that the statistical analysis had been validated by an internationallly recognised scientific body, ECHA experts and the majority of the EFF WG.

The Commission suggested to delete the last paragraph (and subparagrphs) of Section 1, since this text was not necessary for the purpose of the opinion. BPC members agreed by consensus (with the abstention of DE CA) on the text of the draft opinion (including the suggestion of the Commission), where it was concluded that the conditions of Article 19(b)(i) were met for this product.

Actions:

- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and forward the adopted opinion to COM by **9 November 2018**.

10. Any Other Business

The Chairman informed about the ECHA 'survey on pre-natal developmental toxicity (PNDT) tesing' and encouraged the members to participate in the survey.

11. Agreement of the action points and conclusions

Part II contains the main conclusions and action points which were agreed at the meeting.

Part II - Main conclusions and action points

Agreed at the 27th meeting of BPC

16-18 October 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-26	
The revised version of the minutes of BPC-26 was agreed as proposed.	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website.
Item 5 – Administrative issues	
-	
Item 6 - Work programme for BPC	
6.1 Revised Work Programme 2018-2019 **6.2 Outlook for BPC** **6.3 Status harmonised classification and labelling for active substances**	
	Members: to send information on any further changes to the Work Programme (WP) and on the overview of the status on harmonised classification and labelling for active substances to the SECR by **2 November 2018.** **SECR:** i) on the basis of the changes to update the WP on the ECHA website and in the BPC CIRCABC IG.; ii) provide an update the status of harmonised classification and labelling for active substances for the next BPC meeting; iii) to provide a similar overview for PBT and ED assessments for active substances. **SECR:** to upload the presentation on CLH on the BPC CIRCABC IG

Item 7 - Applications for approval of active substances	
7.1.1 Template BPC opinion for active substance approval	
Some suggestions were discussed and decided upon on the template.	**SECR**: to provide a revised template for the next BPC.
7.1.2 Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval	
-	
7.2 Draft BPC opinion on silver zinc zeolite for PT 2, 4, 7 and 9	
The BPC discussed the opinions on silver zinc zeolite for PT 2, 4, 7 and 9.	**SECR:** to schedule the second discussion on these opinions in consultation with the rapporteur
7.3 Draft BPC opinion on silver zeolite for PT 2, 4, 7 and 9	
PT 2: The BPC adopted by consensus the opinion for the non-approval of the active substance/PT combination. **PT 7:** The BPC adopted by consensus the opinion for the non-approval of the active substance/PT combination. The BPC discussed the opinions on silver zeolite for PT 4 and 9.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **30 November 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 **9 November 2018** and publish it on the ECHA website. **SECR:** to schedule the second discussion on the opinions on silver zeolite for PT 4 and 9 in consultation with the rapporteur.
7.4 Draft BPC opinion on silver copper zeolite for PT 2, 4, 7 and 9	
PT 2: The BPC adopted by consensus the opinion for the non-approval of the active substance/PT combination. **PT 7:** The BPC adopted by consensus the opinion for the non-approval of the active substance/PT combination. The BPC discussed the opinions on silver copper zeolite for PT 4 and 9.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **30 November 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 **9 November 2018** and publish it on the ECHA website. **SECR:** to schedule the second discussion on the opinions on silver copper zeolite for PT 4 and 9 in consultation with the rapporteur.
7.5 Draft BPC opinion on silver sodium hydrogen zirconium phosphate for PT 2, 4, 7 and 9	
PT 2: The BPC adopted by consensus the opinion for the non-approval of the active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **30 November 2018.**

PT 7: The BPC adopted by consensus the opinion for the non-approval of the active substance/PT combination. The BPC discussed the opinions on silver sodium hydrogen zirconium phosphate for PT 4 and 9.	**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 **9 November 2018** and publish it on the ECHA website. **SECR:** to schedule the second discussion on the opinions on silver sodium hydrogen zirconium phosphate for PT 4 and 9 in consultation with the rapporteur.
7.6 Revised Assessment Report following the submission of data after active substance approval	
7.6.1 Formaldehyde PT 3	
The member from DE informed the BPC about the evaluation of the data submitted after the approval.	**Member (DE):** to forward the revised assessment report with the List of Endpoints to the SECR by **30 November 2018**.
7.6.2 Margosa extract, cold-pressed oil of Azadirachta indica seeds without shells extracted with super-critical carbon dioxide PT 19	
The member from DE informed the BPC about the evaluation of the data submitted after the approval.	**Member (DE):** to forward the revised assessment report with the List of Endpoints to the SECR by **30 November 2018.**
7.6.3 2-octyl-isothiazol-3(2H)-one (OIT) PT 8	
The member from UK informed the BPC about the evaluation of the data submitted after the approval.	**Member (UK):** to forward the revised assessment report with the List of Endpoints to the SECR by **30 November 2018.**
7.6.4 epsilon-Momfluorothrin PT 18	
The member from UK informed the BPC about the evaluation of the data submitted after the approval.	**Member (UK):** to forward the revised assessment report with the List of Endpoints to the SECR by **30 November 2018.**
7.6.5 Bacillus thuringiensis subsp. Kurstaki PT 18	
The member from FR informed the BPC about the progress on the evaluation of the data submitted after the approval. The BPC discussed and concluded on the information necessary for the products.	**Member (FR):** to forward the revised assessment report with the List of Endpoints for the SECR by **30 November 2018.**
7.7 Requesting further information as new test guidelines become available	
The BPC discussed the document.	**Members**: to consider the active substances for which they are eCA and inform the SECR by **9 November 2018** if there are similar cases to the two presented in the document (local effects driving the assessment and limited data package on mutagenicity leading to a probable data request).

	SECR: to revise the document and publish it on BPC CIRCABC IG.
7.8 Terminology primary and secondary exposure in the BPC opinion	
The BPC agreed on the document.	**SECR:** to publish the document on BPC CIRCABC IG.
7.9 Systematic literature review for ED assessment	
The BPC discussed the document.	**SECR:** to provide a revised document to 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 the BPC CIRCABC IG.
8.2 Draft BPC opinions on Union authorisation applications for a product family containing iodine / PVP-iodine	
The BPC adopted by consensus 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 **29 October 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 **30 October 2018**. **SECR**: to forward the translated draft SPC to COM by **3 December 2018**.
8.3 Working procedure for applications for major change of a Union authorisation	
The BPC agreed on the document.	**SECR:** to revise the document and publish it on BPC CIRCABC IG.
8.4 Union authorisation major change applications: cooperation during the evaluation stage	
The BPC agreed on the document.	**SECR:** to revise the document and publish it on BPC CIRCABC IG.

Item 9 – Article 38 opinions	
9.1 Draft BPC opinion on Questions on unresolved objections during mutual recognition of a PT 18 biocidal product family containing 1R-trans phenothrin for use against ants"	
The BPC adopted by consensus the opinion.	**SECR:** to revise the draft opinion in accordance with the discussions in the BPC and forward the adopted opinion to COM by **9 November 2018**.
Item 10 – Any other business	
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Part III - List of Attendees

Members	European Commission
BORGES Teresa (PT)	CHATELIN Ludovic (DG SANTE)
BORG-GALEA Joanne (MT)	
BROVKINA Julija (LV)	
BROWN Finbar (IE)	
CEBASEK Petra (SI)	**Advisers**
COSTIGAN Michael (UK)	CHEZEAU Aurelie (FR)
DRAGOIU Simona (RO)	FRANK Ulrike (SE)
GAVRIEL Alexandros (CY)	GAUSTAD Astrid (NO)
GONZALEZ MARQUEZ Maria Luisa (ES)	HÄMÄLÄINEN Anna-Maija (FI)
GREGERSEN Nina Falk (DK)	SKOU CORDUA Birgitte (DK)
HAHLBECK Edda (SE)	SCHMALHOLZ Ellen
JAGER Stefanie (DE)	WEINHEIMER Viola (DE)
JOHN Nina (AT)	
KOIVISTO Sanna (FI)	**Accredited Stakeholder Observers**
LANS Martine (NL)	MIHAI Camelia (Cefic)
MERISTE Anu (EE)	
MIKOLASKOVA Denisa (SK)	
RANDALL Marit (NO)	**ECHA Staff**
RUSCONI Manuel (CH)	AIRAKSINEN Antero
VAGIAS Vasileios (EL)	JANKA Adel
VAN BERLO Boris (BE)	KURONEN Terhi
VRHOVAC FILIPOVIC Ivana (HR)	MULLER Gesine
ZIGRAND Jeff (LU)	LOPEZ SERRANO Paloma
	PAPADAKI Paschalina
	RUGGERI Laura
Alternate members	SZYMANKIEWICZ Katarzyna
COLLET Romy (FR)	VAN DE PLASSCHE Erik
CRESTI Raffaella (IT)	VAN GALEN Joost
HUSZAL Sylwester (PL)	WEBER Jan
MIKOLAS Jan (CZ)	
SZENTGYORGYI Timea (HU)	

Applicants	Apologies
EU BPR Silver Task Force	-
Novadan ApS	
Sumitomo Chemical Agro Europe SAS	

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-27

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-27 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2	BPC-A-27-2017_rev1	Draft agenda	
4	BPC-M-26-2018	Draft minutes from BPC-26	
5.2	BPC-27-2018-01	Administrative issues and report from the other Committees	
6.1	BPC-27-2018-02	BPC updated Work Programme 2017-2018	
6.2	BPC-27-2018-03	Outlook for the BPC	
6.3	BPC-27-2018-04	Status harmonised classification and labelling for active substances	
7.1	BPC-27-2018-05	7.1.1. Template BPC opinion for active substance approval	
	BPC-27-2018-06	7.1.2. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval	
7.6	BPC-27-2018-24	7.6.1. Formaldehyde for PT 3	
	BPC-27-2018-25	7.6.2. Margosa extract, cold-pressed oil of Azadirachta indica seeds without shells extracted with super-critical carbon dioxide for PT 19	
	BPC-27-2018-26	7.6.3. 2-octyl-isothiazol-3(2H)-one (OIT) for PT 8	
	BPC-27-2018-27	7.6.4. epsilon-Momfluorothrin for PT 18	
	BPC-27-2018-28A	7.6.5. Bacillus thuringiensis subsp. kurstaki, serotype 3a3b, strain ABTS-351 for PT 18	Summary by FR
	BPC-27-2018-28B		Revised AR
	BPC-27-2018-28C		Doc IIIA
	BPC-27-2018-28D		Doc II
	BPC-27-2018-28E		Addeneum to Doc II
	BPC-27-2018-45_Room doc 6		Additional doc by FR

7.7	BPC-27-2018-29	Requesting further information as new test guidelines become available	
7.8	BPC-27-2018-30	Terminology primary and secondary exposure in the BPC opinion	
7.9	BPC-27-2018-07	Systematic literature review for ED assessment	
8.3	BPC-27-2018-32	Working procedure for applications for major change of a Union authorisation	
8.4	BPC-27-2018-33	Union authorisation major change applications: cooperation during the evaluation stage	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.2	BPC-27-2018-08A	Silver zinc zeolite – PT 2	Draft BPC opinion
	BPC-27-2018-08B		Assessment report
	BPC-27-2018-08C		Open issues
	BPC-27-2018-35		Background paper by SE
	BPC-27-2018-36		SECR Overview treated articles
	BPC-27-2018-37		Details of EFF assessment
	BPC-27-2018-38		Efficacy guidance on Treated Articles
	BPC-27-2018-39		Letter from Appl to ECHA
	BPC-27-2018-40_Room doc_1		ECHA reply to Appl letter
	BPC-27-2018-41_Room doc_2		SZZ PT 4 Food contact summary
	BPC-27-2018-42_Room doc_3		Silver PT 9 textiles summary
	BPC-27-2018-43_Room doc_4		Letter from Appl to ECHA of 14/10/2018
	BPC-27-2018-44_Room doc_5		Exposure scales /treated articles
	BPC-27-2018-09A	Silver zinc zeolite – PT 4	Draft BPC opinion
	BPC-27-2018-08B		Assessment report
	BPC-27-2018-08C		Open issues
	BPC-27-2018-10A	Silver zinc zeolite – PT 7	Draft BPC opinion
	BPC-27-2018-08B		Assessment report
	BPC-27-2018-08C		Open issues
	BPC-27-2018-11A	Silver zinc zeolite – PT 9	Draft BPC opinion
	BPC-27-2018-08B		Assessment report
	BPC-27-2018-08C		Open issues
7.3	BPC-27-2018-12A	Silver zeolite - PT 2	Draft BPC opinion
	BPC-27-2018-12B		Assessment report
	BPC-27-2018-12C		Open issues
	BPC-27-2018-13A		Draft BPC opinion

	BPC-27-2018-12B	Silver zeolite - PT 4	Assessment report
	BPC-27-2018-12C		Open issues
	BPC-27-2018-14A	Silver zeolite - PT 7	Draft BPC opinion
	BPC-27-2018-12B		Assessment report
	BPC-27-2018-12C		Open issues
	BPC-27-2018-15A	Silver zeolite - PT 9	Draft BPC opinion
	BPC-27-2018-12B		Assessment report
	BPC-27-2018-12C		Open issues
7.4	BPC-27-2018-16A	Silver copper zeolite - PT 2	Draft BPC opinion
	BPC-27-2018-16B		Assessment report
	BPC-27-2018-16C		Open issues
	BPC-27-2018-17A	Silver copper zeolite - PT 4	Draft BPC opinion
	BPC-27-2018-16B		Assessment report
	BPC-27-2018-16C		Open issues
	BPC-27-2018-18A	Silver copper zeolite - PT 7	Draft BPC opinion
	BPC-27-2018-16B		Assessment report
	BPC-27-2018-16C		Open issues
	BPC-27-2018-19A	Silver copper zeolite - PT 9	Draft BPC opinion
	BPC-27-2018-16B		Assessment report
	BPC-27-2018-16C		Open issues
7.5	BPC-27-2018-20A	Silver sodium hydrogen zirconium phosphate - PT 2	Draft BPC opinion
	BPC-27-2018-20B		Assessment report
	BPC-27-2018-20C		Open issues
	BPC-27-2018-21A	Silver sodium hydrogen zirconium phosphate - PT 4	Draft BPC opinion
	BPC-27-2018-20B		Assessment report
	BPC-27-2018-20C		Open issues
	BPC-27-2018-22A	Silver sodium hydrogen zirconium phosphate - PT 7	Draft BPC opinion
	BPC-27-2018-20B		Assessment report
	BPC-27-2018-20C		Open issues
	BPC-27-2018-23A	Silver sodium hydrogen zirconium phosphate - PT 9	Draft BPC opinion
	BPC-27-2018-20B		Assessment report
	BPC-27-2018-20C		Open issues
8.2	BPC-27-2018-31A	UA: product families containing iodine / PVP-iodine	Draft BPC opinion
	BPC-27-2018-31B		SPC
	BPC-27-2018-31C		PAR
	BPC-27-2018-31C1		Confidential annex to PAR
	BPC-27-2018-31C2		Confidential annex MS to PAR

	BPC-27-2018-31C		Open issues
9.1	BPC-27-2018-34A	Questions on unresolved objections during mutual recognition of a PT 18 biocidal product family containing 1R-trans phenothrin for use against ants”	Draft BPC opinion

5 October 2018
BPC-A-27-2018_rev1

Draft agenda
27th meeting of the Biocidal Products Committee (BPC)
16-18 October 2018
ECHA Conference Centre, Annankatu 18, Helsinki
Starts on 16 October at 09:30, ends on 18 October at 16:00

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-27-2018_rev1
For agreement

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

4. – Agreement of the minutes and review of actions from BPC-26

BPC-M-26-2018
For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

BPC-27-2018-01
For information

6. – Work programme for BPC

6.1. Revised BPC Work Programme 2018-2019

BPC-27-2018-02
For information

6.2. Outlook for BPC

BPC-27-2018-03

For information

6.3. Status harmonised classification and labelling for active substances

BPC-27-2018-04

For information

7. – Applications for approval of active substances*

7.1. Procedural and administrative aspects:

7.1.1. Template BPC opinion for active substance approval

BPC-27-2018-05

For information

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

BPC-27-2018-06

For information

7.2. Draft BPC opinion on silver zinc zeolite for PT 2, 4, 7 and 9

Previous discussion(s): TM-II-2013, TM-IV-2013, WG-III-2015, WG-III-2016,WG-V-2016, WG-V-2017

PT 2: BPC-27-2018-08A, B, C, BPC-27-2018-35

PT 4: BPC-27-2018-09A, 08B, 09C

PT 7: BPC-27-2018-10A, 08B, 10C

PT 9: BPC-27-2018-11A, 08B, 11C

For agreement

7.3. Draft BPC opinion on silver zeolite for PT 2, 4, 7 and 9

Previous discussion(s): WG-V-2017

PT 2: BPC-27-2018-12A, B, C

PT 4: BPC-27-2018-13A, 12B, 13C

PT 7: BPC-27-2018-14A, 12B, 14C

PT 9: BPC-27-2018-15A, 12B, 15C

For adoption

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

7.4. Draft BPC opinion on silver copper zeolite for PT 2, 4, 7 and 9

Previous discussion(s): WG-V-2017

PT 2: BPC-27-2018-16A, B, C
PT 4: BPC-27-2018-17A, 16B, 17C
PT 7: BPC-27-2018-18A, 16B, 18C
PT 9: BPC-27-2018-19A, 16B, 19C

For adoption

7.5. Draft BPC opinion on silver sodium hydrogen zirconium phosphate for PT 2, 4, 7 and 9

Previous discussion(s): WG-V-2017

PT 2: BPC-27-2018-20A, B, C
PT 4: BPC-27-2018-21A, 20B, 21C
PT 7: BPC-27-2018-22A, 20B, 22C
PT 9: BPC-27-2018-23A, 20B, 23C

For adoption

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

7.6.1. Formaldehyde for PT 3

BPC-27-2018-24

For agreement

7.6.2. Margosa extract, cold-pressed oil of *Azadirachta indica* seeds without shells extracted with super-critical carbon dioxide for PT 19

BPC-27-2018-25

For agreement

7.6.3. 2-octyl-isothiazol-3(2H)-one (OIT) for PT 8

BPC-27-2018-26

For agreement

7.6.4. *epsilon*-Momfluorothrin for PT 18

BPC-27-2018-27

For agreement

7.6.5. *Bacillus thuringiensis* subsp. *kurstaki*, serotype 3a3b, strain ABTS-351 for PT 18

BPC-27-2018-28

For agreement

7.7. Requesting further information as new test guidelines become available

BPC-27-2018-29

For agreement

7.8. Terminology primary and secondary exposure in the BPC opinion

BPC-27-2018-30

For agreement

7.9. Systmatic literature review for ED assessment

BPC-27-2018-07

For discussion

Item 8 – Union authorisation**

8.1 Update on Union authorisation

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

Previous discussion(s): WG-IV-2018

BPC-27-2018-31A, B, C, D

For adoption

8.3 Working procedure for applications for major change of a Union authorisation

BPC-27-2018-32

For agreement

8.4 Union authorisation major change applications: cooperation during the evaluation stage

BPC-27-2018-33

For agreement

Item 9 – Article 38 opinions

9.1 Draft BPC opinion on "Questions on unresolved objections during mutual recognition of a PT 18 biocidal product family containing 1R-trans phenothrin for use against ants"

BPC-27-2018-34A

For adoption

** For the discussions of the draft BPC opinions at least the following documents will be distributed: a draft BPC opinion (denoted by A), a draft Summary of Product Characteristics (SPC) (denoted by B), a draft product assessment report (PAR) (denoted by C) and a document containing open issues to be discussed for the biocidal product or biocidal product familiy (denoted by D).

Item 10 – Any other business

Item 11 – Action points and conclusions

For agreement

Provisional time schedule for the

27th meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Annankatu 18, Helsinki

16 October 2018: starts at 09:30; 18 October 2018 ends at 16:00

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

Tuesday 16 October: morning session

Items 1-5	Opening items and administrative issues	
Item 6	Work programme of the BPC 2018-2019	
Item 7.1	Procedural and administrative aspects:	
	7.1.1.	Template BPC opinion for active substance approval
	7.1.2.	Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval
Item 7.7	Requesting further information as new test guidelines become available	
Item 7.8	Terminology primary and secondary exposure in the BPC opinion	
Item 7.9	Systmatic literature review for ED assessment	

Tuesday 16 October: afternoon session

Item 7.2-7.5	BPC opinions on silver:	
	7.2.	Draft BPC opinion on silver zinc zeolite for PT 2, 4, 7 and 9
	7.3.	Draft BPC opinion on silver zeolite for PT 2, 4, 7 and 9
	7.4.	Draft BPC opinion on silver copper zeolite for PT 2, 4, 7 and 9
	7.5.	Draft BPC opinion on silver sodium hydrogen zirconium phosphate for PT 2, 4, 7 and 9

Wednesday 17 October: morning session

Item 7.2-7.5 Draft BPC opinions on silver (continued)

Wednesday 17 October: afternoon session

Item 7.2-7.5 Draft BPC opinions on silver (continued)

Thursday 18 October: morning session

Item 7.6	Revised Assessment Report following the submission of data after active substance approval:
	7.6.1. Formaldehyde for PT 3
	7.6.2. Margosa extract, cold-pressed oil of Azadirachta indica seeds without shells extracted with super-critical carbon dioxide for PT 19
	7.6.3. 2-octyl-isothiazol-3(2H)-one (OIT) for PT 8
	7.6.4. epsilon-Momfluorothrin for PT 18
	7.6.5. Bacillus thuringiensis subsp. kurstaki, serotype 3a3b, strain ABTS-351for PT 18
Item 8.1	Update on Union authorisation
Item 8.2	Draft BPC opinions on Union authorisation applications for a product family containing iodine / PVP-iodine
Item 8.3	Working procedure for applications for major change of a Union authorisation
Item 8.4	Union authorisation major change applications: cooperation during the evaluation stage

Thursday 18 October: afternoon session

Item 9.1	Draft BPC opinion on “Questions on unresolved objections during mutual recognition of a PT 18 biocidal product family containing 1R-trans phenothrin for use against ants”
Item 10	AOB
Item 11	Action points and conclusions

End of meeting

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