6 March 2018

BPC-M-23-2017

Minutes of the 23rd meeting of the Biocidal Products Committee (BPC)

11-14 December 2017

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chairman of the Biocidal Products Committee (BPC) welcomed the participants to the 23rd BPC meeting.

Regarding the BPC membership, the Chairman stated that there is a new BPC member from the Netherlands: Martine Lans and a new alternate member from Ireland: Stephen Carberry. In addition, the Greek BPC member Athanasios Zounos has resigned and the BPC Secretariat is waiting Greece to appoint a new member.

The Chairman then informed the BPC members of the participation of 27 members, including 7 alternates.

14 advisers and 2 representatives from accredited stakeholder organisations (ASOs) were present at the meeting. One representative from the European Commission also attended the meeting. Apologies were received from 1 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-23-2017_rev1) 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 closed agenda items: Item 7.8, 7.9, 8.2 and 9.1.

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-22

The revised draft minutes from BPC-22 (BPC-M-22-2017), incorporating the comments received from members, were agreed. The late comments to minutes from COM will still need to be addressed which will be done in close communication with COM.

Following a comment by one of the members on the minutes for agenda item 7.2 (draft BPC opinion on azoxystrobin for PT 7, 9 and 10) it was agreed that BPC SECR will clarify if the preservation of mineral sealants and grouts falls under PT 7 or PT 10.

The Chairman noted that the actions from BPC-22 have been carried out.

The Chairman informed the meeting on:

- ArtFood guidance:

i) the guidance on estimating dietary risk from transfer if biocidal active substances into food – non-professional uses has been published as a new section 5 in volume III Human Health – Assessment & Evaluation (Parts B+C) as version 3.0 in November 2017;

ii) the guidance on livestock exposure will be published in the near future; iii) for the professional users the draft guidance needs to substantially revised in light of the interim approach and new information so no time schedule is available for publication of this part.

- the discussion at the last CA meeting on the new ED criteria:

The Chairman informed the meeting about the consequences of the new criteria for endocrine-disrupting properties as laid down in Regulation (EU) 2017/2100 for the adoption of the BPC opinions on active substance approval. Following a presentation by the Chairman on this subject several questions were raised. First of all it was confirmed by the Chairman that opinions scheduled for BPC 24, 25 and 26 will be returned to ECHA by the Commission if the evaluation does not contain an assessment according to the new criteria with some exceptions as indicated in the presentation. Up to now, it is unclear whether the COM will also return opinions of active substances which fulfil any of the other exclusion criteria. In contrast, in case of a non-approval proposal because of unacceptable risks the opinion will not be returned to ECHA. Following another question it was discussed in which cases the eCA may request scientific advice from the ED Expert Group. The Chairman confirmed that the foreseen procedure is that the Human Health and Environment Working Groups will conclude if an active substance is considered as having endocrine-disrupting properties with respect to respectively humans (part A) or non-target organisms (part B) as laid down in the Annex of Regulation (EU) 2017/2100. Subsequently, the BPC will conclude whether the active substance is a candidate for substitution or meets the exclusion criteria. COM also indicated that procedural guidance for ED assessment are also under discussion at CA level.

Actions:

- **SECR:** to upload the agreed minutes from BPC-22 to the BPC CIRCABC IG and to the ECHA website after the meeting.
- **SECR**: to upload the presentation “Report back and follow-up CA meeting: endocrine disrupters” to S-CIRCABC.
- **SECR**: to clarify if the preservation of mineral sealants and grouts fall under PT 7 or PT 10.

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 meeting that the templates of declarations, which members sign (eg annual declaration of interest), have been slightly modified and the declaration procedure has been simplified. The changes have been approved by the Management Board. Accordingly, the Rules of Procedure will be revised and the new declaration templates will be available from the ECHA website.

The Chairman introduced document BPC-23-2017-01 covering the administrative updates and the report from the other ECHA Committees, provided to members for information purposes. The Chairman indicated that from the next meeting onwards this document will be replaced by a presentation prepared by ECHA for the Management Board meeting which contains the progress reports for each Committee including both the PBT and the ED Expert Group. This measure was taken by all Committees to rationalise the reporting.

6. Work Programme for BPC

6.1 BPC Work Programme 2017-2018

6.2 Outlook for the BPC

The Chairman informed the members that the Work Programme was revised after the last BPC meeting and uploaded to CIRCABC. 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 are invited to contact the SECR on possible changes by 12 January 2018 after which a revised version will be published on the ECHA website.

The Chairman stated that:

- For active substance approval the number of opinions adopted so far for the Review Programme is 29 whereas the total is 39. This is below the objective of 50 for the Review Programme;
- For Union authorisation the Chairman referred to agenda item 8.

The Chairman also informed the meeting that with respect to active substance approval:

- Almost no CARs were submitted during the last process flows;
- At the last CA meeting the progress of the Review Programme was discussed and actions were agreed upon for MSCAs, ECHA and COM.

Similarly to previous BPC meetings, COM voiced concerns the work achived this year is far below the target (50 opinions on the review programme), 20 % less opinions than last year on the review programme was delivered. Discussions continues in the CA meeting and BPC members should take any action to improve the situation. Another issue concerns the backlog reports submitted before 1st September 2013, as it becomes less and less acceptable to still have these reports unconcluded. Actions must be taken by the BPC and the relevant eCA to conclude on these reports.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) to the SECR by **12 January 2018**.
- **SECR**: on the basis of the changes to update the work programme on the ECHA website and in the BPC CIRCABC IG.

7. Applications for approval of active substances

7.1. Templates and formats for active substance approval: catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval

The Chairman stated that no revised document was prepared by the SECR.

7.2 Draft BPC opinion on cholecalciferol for PT 14

The Chairman welcomed the applicant for this item. The rapporteur presented the current status of the active substance after the BPC-21 meeting and subsequent public consultation.

The Chairman noted that the Regulation (EU) No 2017/2100 on the assessment of endocrine disruption (ED) properties needs to be taken into account since the vote on a Commission decision on the approval of the active substance will take place in the Standing Committee after the date of application of the ED criteria (7 June 2018), and the new criteria will be applicable for product authorisation according to the BPR. This was confirmed by the Commission, who supported that a conclusion on the fulfilment of the ED criteria is included in the BPC opinion at this point in time, so that time can be saved in the process.

The discussion focussed on:

- Assessment of endocrine disrupting properties

The rapporteur considered that cholecalciferol being a hormone fulfils the criteria for having endocrine disrupting properties laid down in Article 5(1)d of Regulation (EU) No 528/2012 and defined in sections A and B of the Annex to the Regulation (EU) No 2017/2100. As a consequence,the active substance meets one of the criteria for exclusion stated in Article 5(1) of the BPR. The rapporteur noted that in the exclusion criteria there is no consideration on whether or not exposure is negligible. The rapporteur also mentioned that the criteria mentioned in Section B of the Annex to the Regulation (EU) No 2017/2100 do not mention that endogenous substances controlling the endocrine mechanism of vertebrate animals are exempted.

The Commission stated that the ED criteria shall be applied as they were defined and that a discussion will follow at the Standing Committee for Biocidal Products on whether the derogation from exclusion stated in Article 5(2) of the BPR would apply for this active substance, so that an approval can be granted.

The BPC members supported the proposal from the rapporteur that this active substance can be considered as having endocrine-disrupting properties. The Chairman noted that therefore the main point for the discussion should be the consequences of this fulfilment. The Chairman also noted that the debate on the application of Article 19(5) of the BPR, which was discussed at BPC-21, would no longer be relevant as cholecalciferol now fulfills now the exclusion criteria.

- Use by the general public

The Chairman informed the meeting about the on-going discussions on the draft note from the Commission on “The implementation of scientific criteria for the determination of endocrine-disrupting properties in the context of biocidal product authorisation” (CA-Nov17-Doc.7.2.c). This may imply that biocidal products containing cholecalciferol might not be used by the general public according to Article 19(4)(d) of Regulation (EU) No 528/2012.

Several BPC members and the applicant stated that the current proposal to differentiate between active substances and co-formulants considered as ED in terms of a threshold concentration for being used by the general public is not scientifically justified. The Chairman mentioned that this issue will be subject to discussions at the Competent Authority meeting and decisions on this point have not yet been made.

The Commission proposed, for this particular case, the BPC opinion could be adopted including the sections related to the use by the general public for consistency with the decisions on the anticoagulant rodenticides. If the decision at the Competent Authority meeting on the note prepared by the Commission entitled "The implementation of scientific criteria for the determination of endocrine-disrupting properties in the context of biocidal product authorisation” , would mean that no products can be allowed for use by the general public, the relevant sections applicable for the general public will then no longer be valid. The BPC meeting agreed to include a disclaimer in the opinion with respect to the application of the new ED criteria for biocidal products and the use by the general public and to refer to the on-going discussion of the Commission document (CA-Nov17-Doc.7.2.c) on this aspect.

- Public consultation

The rapporteur stated that the outcome of comments received during the public consultation is that cholecalciferol is considered as a valuable additional active substance to the use of anticoagulant rodenticides as it has a more favourable toxicological and ecotoxicological profile.

Similarly to previous cases of substances subject to exclusion/substitution, the Commission asked that the BPC opinion includes more conclusive views on the (eco)toxicological profile of cholecalciferol compared with the already approved anticoagulant rodenticides, and on the availability of other rodenticide alternatives, as the BPC has already reviewed all these substances and this would facilitate the discussion at the Standing Committee on the derogation of Article 5(2). The Chairman suggested to

clearly indicate this in Section 2.2.3 of the BPC opinion. A BPC member noted that the fact that cholecalciferol meets the criteria for being an endocrine disruptor should be taken into account when considering this substance as an alternative to the AVK rodenticides.

ECHA also reported on additional information available about the potential for dog poisoning that could be taken into consideration during the authorisation of cholecalciferol-containing products. The BPC meeting agreed that the risks for dog poisoning are covered by the proposal from the rapporteur about pets as stated in Section 2.4 of the BPC opinion.

The rest of open issues in the assessment report (AR) and the opinion were then discussed and the agreements are described in the open issues table. The BPC concluded that Articles 10(1)(a) and Articles 10(1)(e) of the BPC apply as the substance fulfils the endocrine-disrupting criteria.

The Assessment Report and the BPC opinion 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 **26 January 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 **12 January 2018** and publish it on the ECHA website.

7.3 Draft BPC opinion on formaldehyde for PT 2

The applicant was not present at the discussion of this item. The ASOs were allowed to be present. The rapporteur introduced the substance and the general issues related to the assessment report (AR) and the opinion were then discussed in detail (modifications are described in the open issues table).

The rapporteur explained that the formaldehyde PT 2 opinion was scheduled for discussion at BPC-13 but was withdrawn (after the pre-BPC commenting period), as there was no safe use for environment and no risk mitigation measure (RMM) could be proposed. Since then the eCA has not made any amendments in the risk assessment but introduced a RMM preventing exposure of waste water to the STP for the scenario “room disinfection by fogging/fumigation in epidemic cases” therefore, achieving a safe use scenario.

The Chairman explained that at this stage it is unclear whether the ED criteria will need to be assessed but the BPC can adopt the opinion at this meeting and forward it to the COM.

With regard to the public consultation, the COM mentioned that the BPC should bring their expertise forward when looking at the possible alternatives as it should be a clear added value in the BPC review. The eCA remarked that the contributions received from the public are not necessarily useful in identifying alternatives. It was agreed to include some information on active substances already approved for the same use.

The assessment report was agreed by the BPC. The BPC opinion on the application for the approval of formaldehyde for PT2 was adopted by consensus. According to the “Note on the principles for taking decisions on the approval of active substances under the BPR” for evaluation reports submitted by the eCA before 1 September 2013, the exclusion and

substitution criteria as defined in the BPR have to be assessed, but the principles of the Biocidal Products Directive will apply for the decision-making. This means that though formaldeyhde fullfills Article 5(1)(a) of Regulation (EU) No 528/2012, Article 5(2) of Regulation (EU) No 528/2012 is not of relevance for the approval decision.

A member added that they are aware that laboratories where biological agents are used/tested use formaldehyde to disinfect rooms by fumigation. Consequently, given the very limited use that has been identified as safe, this could be a significant issue in the future for the control of dangerous pathogens, when products containing formaldehyde for disinfection of laboratories are subject to authorisation under BPR. Maybe action/awareness raising for this sector needs to be undertaken now in advance of the approval date.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the BPC Secretariat by **26 January 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 **12 January 2018** and publish it on the ECHA website.

7.4 Draft BPC opinion on empenthrin for PT 18

The Chairman welcomed the applicant for this item. The rapporteur introduced the substance and made a statement in response to the “Paper on the Draft Biocidal Products Committee ('BPC') opinion proposing the non approval of empenthrin presented on behalf of Sumitomo Chemical (UK) Plc.” from the applicant.

The rapporteur explained the following[1]:

The 1st draft CAR submitted in 2014 failed the accordance check, since no CLH dossier had been submitted.

The applicant submitted a new waiver on carcinogenicity in December 2015, after having been informed by the eCA that the active substance would face a non-approval with the original waiver. This 2nd waiver was rejected during the early Human Health WG discussion in January 2016. The eCA then asked whether the applicant would be willing to submit a 2 years rat carcinogenicity study (with a sufficiently long stop-the-clock).

On 17 February 2016 the applicant informed the eCA that they would not perform a 2-year rat carcinogenicity study on empenthrin and instead would submit a 3rd waiver (more robust read-across and QSAR with other pyrethroids). The eCA then stressed that if this 3rd waiver was to be rejected by the Human Health WG it would represent a substantial data gap.

The eCA assessed the 3rd waiver and considered it to be unacceptable. Thus, as a result of this data gap the eCA could not conclude on the assessment of the exclusion criterion for empenthrin.

[1] A detailed statement of the rapporteur is added as an annex to the confidential minutes.

The 3rd waiver was included in the revised draft CAR (submitted for commenting on 24 June 2016) where the eCA proposed non-approval for empenthrin as an active substance in PT 18.

The Human Health WG agreed that the risk assessment could be performed in the absence of carcinogenicity data, if an additional AF of 10 was applied to address the remaining uncertainty arising from the absence of a carcinogenicity study. However , unacceptable risks for human health were identified.

Thereafter, the general issues related to the assessment report (AR) and the opinion were discussed in detail (modifications are described in the open issues table).

During the discussion, the applicant stated that they had not been made aware of the possibility to perform carcinogenicity studies (after the early WG TOX meeting in 2016 when the 2nd carcinogenicity waiver was discussed). The Chairman pointed out that the peer review process took place according to the working procedure for the active substance approval process and stated that the applicant had been present at the early WG TOX meeting. Furthermore the Chairman reiterated the conclusion that since carcinogenicity data is lacking, the exclusion criteria cannot be assessed. Also the COM reminded the meeting of the need to follow the procedures and timelines of the peer review process, which include specific deadlines for submission of data.

The Chairman then asked the BPC members whether they agreed with the eCA proposal to continue with the adoption of the opinion for non-approval or the applicant proposal to bring the substance back to the Human Health WG for a further discussion. The BPC agreed to continue with the adoption of the opinion.

The assessment report was agreed by the BPC. The BPC opinion on the non-approval of empenthrin for PT 18 was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the BPC Secretariat by **26 January 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 **12 January 2018** and publish it on the ECHA website.

7.5 Draft BPC opinion on cyphenothrin for PT 18

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

The applicant raised the issue of the persistence of cyphenothrin, requesting the consultation of the PBT Expert Group, because in the opinion of the applicant cyphenothrin does not meet the P criterion (contrary to what was concluded by the Environment Working Group). The applicant referred to evidence submitted during the public consultation and to newly available studies on degradation in soil. The Chairman stated that at the

Environmental WG there was a consensus opinion that cyphenothrin meets the P criterion. The Chairman clarified that in such clear cases there is according to the SECR no need to consult the PBT Expert Group. This existing practice will be further clarified in the working procedures.

Referring to the new studies on degradation in soil, it was stated that new additional data can be provided at product authorisation, where it will be evaluated by the rMS (for national authorisation) or the eCA (for Union authorisation). This may lead to a change in the List of Endpoints (LoEP). COM indicated that the applicant could consider applying for an amendment of the conditions of approval based on Article 7(1) of the BPR, which can be done any time.

The description of the environmental scenarios for the different representative products and uses was extensively discussed. It was agreed to describe more clearly in the opinion the different application methods, treatments and the resulting risks for the different compartments for cyphenothrin and its metabolites. As unacceptable risks were identified for one of the metabolites for secondary poisoning of worm-eating mammals following indoor suface treatment, it was agreed to highlight this in the conditions listed in section 2.3 of the opinion.

The assessment report was agreed by the BPC. The BPC opinion on the application for the approval of cyphenothrin for PT 18 was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the BPC Secretariat by **26 January 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 **12 January 2018** and publish it on the ECHA website.

7.6 Draft BPC opinion on penflufen for PT 8

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 opinions were then discussed in detail (modifications are described in the open issues table).

It was agreed that one of the impurities is not relevant, which is in line with an on-going evaluation under PPP by EFSA.

The applicant mentioned that the required information mentioned in section 2.5 of the opinion is available and will be submitted to the eCA.

The assessment report was agreed by the BPC. The BPC opinion on the application for the approval of penflufen for PT8 was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the BPC Secretariat by **26 January 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 **12 January 2018** and publish it on the ECHA website.

7.7 Outcome written procedure on the adoption of the BPC opinion on acetamiprid for PT 18

The Chairman informed the meeting that it was agreed at BPC-18 to adopt the opinion by written procedure. The written procedure was launched in October 2017 and resulted in agreement by all responding BPC members except one. This member stated that one of the agreements following discussions of the Human Health Working Group was not included in the assessment and draft opinion. As a result, new calculations were performed which resulted in an unacceptable risk being identified. Consequently more restrictive risk mitigation measure were applied by the eCA in a revised risk assessment in order to mitigate the unacceptable risk. These amendments were presented in a revised opinion which was distributed as room document at the BPC meeting for discussion and subsequently agreed upon.

The BPC opinion on the application for the approval of acetamiprid for PT 18 was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **26 January 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 **12 January 2018** and publish it on the ECHA website.

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

The meeting agreed on the revised Assessment Reports including the list of endpoints for the agenda items 7.8.1 to 7.8.4.

7.8.1 MBIT for PT 6

Actions:

- **Member (PL):** to forward the revised assessment report including the list of endpoints to the SECR by **26 January 2018**.

7.8.2 DCPP for PT 1, 2 and 4

Actions:

- **Member (AT):** to forward the revised assessment report including the list of endpoints to the SECR by **26 January 2018**.

7.8.3 CMK for PT 1, 2, 3, 6, 9 and 13

Actions:

- **Member (FR):** to forward the revised assessment report including the list of endpoints to the SECR by **26 January 2018**.

7.8.4 Cyfluthrin for PT 18

Actions:

- **Member (DE):** to forward the revised assessment report including the list of endpoints to the SECR by **26 January 2018**.

7.9 Question eCA (France) on the evaluation of carbon dioxide generated in-situ for PT 19

The meeting agreed on the proposal from the eCA (FR) on the evaluation of carbon dioxide generated in-situ for PT 19. Instead of deriving a reference specification for the precursors reference to national standards will be made. The eCA will incorporate this in the draft CAR to be submitted to ECHA for the peer review process.

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.

Moreover, SECR presented a proposal for a "fast-track approach". When the first Union authorisation applications have been discussed at the Working Groups, the subsequent

applications could be discussed directly at the BPC, if they are based on the same active substance(s), the same use(s) and the same product type(s). A more accurate and in-depth accordance check by SECR is considered for those applications, to ensure that they can be discussed directly at the BPC. Before the BPC, the Working Group members will be given the possibility to comment in writing on the applications. The applicability of the "fast-track" approach will be assessed on a case-by-case basis, depending, among other aspects, on the number of comments received during the commenting phase. The advantage of the "fast-track approach" is to increase the efficiency of the process and reduce the workload for Working Group members. SECR proposed to test this approach for Union authorisation applications based on iodine/PVP-iodine entering the process flow 23. Support was given by several BPC members to further develop the "fast-track" approach for discussion in an upcoming meeting. However, BPC members asked ECHA to establish a newsgroup for commenting.

A member asked about the status of the revision of the working procedure for Union authorisation applications. SECR replied that for the time being no revision is foreseen. The received comments were mainly focused on the improvement of the communications channels and it is considered more appropriate to acquire more experience in processing Union authorisation applications before revising the working procedure.

COM noted that the 3-year deadline to review applications for product authorisation might not be kept for some iodine applications, which is a concern.

Actions:

- **SECR**: to upload the presentation to S-CIRCABC.
- **SECR**: to open a Newsgroup on BPC CIRCABC IG for commenting on proposal for the "fast-track procedure"

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

The BPC opinions on two Union authorisation applications for product families containing iodine / PVP-iodine were adopted by consensus. For both applications, the BPC considered that using the products 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 **11 January 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 **12 January 2018**.
- **SECR:** to forward the translated draft SPC to COM by **12 February 2018**.

9. Article 38 opinions

9.1 Draft BPC opinion on unresolved objections during the mutual recognition of two insect repellents

On 7 September ECHA received a request from the Commission for an opinion according to the provisions of Article 38 of the BPR on several questions related to unresolved issues during the Mutual Recognition (MR) of two insect repellents. ECHA acted as rapporteur for drafting the BPC opinion.

The SECR explained that the initiating concerned MS (icMS) noted that there was a discrepancy between the application rate used in the exposure assessment of the products and that used in the efficacy studies. The application rate used in the exposure assessment had not been proven efficacious and, therefore, the conditions of Article 19(1)(b)(1) were not met for granting the authorisation of the products.

The draft opinion was discussed and several changes to the text were agreed. The majority of BPC members agreed with the conclusions in the draft opinion:

- Considering the applicable guidance at the time of submission of the application, the conditions of Article 19(1)(b)(i) were not met for the two products when used as claimed.
- There is no precise harmonised guidance for the assessment of PT19 products. Even though there is harmonised guidance, this guidance does not clearly specify how to carry out tests at realistic application rates.
- The existence of a precedent with other PT19 products where the discrepancy between the application rate used for the exposure assessment and that used in the efficacy studies was accepted may have led to a misunderstanding by applicants regarding the efficacy data requirements for PT19 applications.

The draft opinion will be amended including the changes agreed by the BPC members.

Adoption of the opinion: The opinion was adopted by majority. Two BPC members, abstained and two members communicated their intention to submit a minority opinion.

Actions:

- **Members (FR and BE):** to submit their minority opinion to SECR by **21 December 2017**.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and forward the adopted opinion to COM by **12 January 2018**.

10. Article 75(1)(g) opinions

10.1 Draft BPC opinion on inclusion into Annex I of corn cob

The Chairman introduced the opinion on corn cob, which was previously discussed at BPC-22 and informed about the changes introduced following the commenting period.

Two BPC members disagreed with the proposal to include powdered corn cob in Annex I as it should not be considered as a substance according to the REACH definition. The SECR explained that based on the manufacturing process, it could be assumed that powdered corn cob undergoes chemical modifications and therefore it should be considered a substance under REACH. COM indicated in this regard that they would take over the decision from the BPC meeting.

A BPC member commented that the opinion lacked information on how the evaluation was performed. The SECR explained that an evaluation of powdered corn cob was already carried out under the Biocidal Products Directive (BPD) and that a re-evaluation was not considered necessary as no new information has become available. As stated in the assessment report prepared under the BPD, powdered corn cob doesn't need classification.

A member suggested to include as a specific provision the same condition that was stated in Annex IA of the BPD as indicated in Directive 2013/44/EU: "Only for use in the form of pellets in dry locations". This would guarantee that powdered corn cob has an action against harmful organisms and therefore fulfils the definition of 'active substance' under the BPR. The meeting agreed to this proposal.

The BPC opinion on powdered corn cob was adopted by majority. Two BPC members filed a minority opinion. DE justified the minority opinion with severe concerns regarding the humaneness of powdered corn cob. The mode of action of the active substance results in unacceptable effects on the target organism and causes unnecessary pain and suffering in the target organism.

Actions:

- **Members (DE and SE):** to submit their minority opinion to SECR by **21 December 2017**.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and forward the adopted opinion to COM by **12 January 2018**.

10.2 Draft BPC opinion on copper sulphate pentahydrate – PT 3

The Chairman welcomed the applicant for this item. The Rapporteur introduced the opinion and informed that following the Efficacy Working Group discussion, copper sulphate pentahydrate is not considered as an active substance in PT 3 in this particular product.

A member pointed out that this substance may have a long lasting effect and act as an active substance and therefore proposed to include a post-approval condition requiring new data when new efficacy guidance is available.

The Chairman clarified that if the BPC concludes that the substance is not an active substance, the question of additional data is no longer relevant. Nevertheless, if such request will be made for similar cases in the future the Efficacy Working Group will take into account all available guidance documents.

The BPC opinion on copper sulphate pentahydrate for PT 3 was adopted by consensus.

Actions:

- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and forward the adopted opinion to COM by **12 January 2018**.

10.3 Draft BPC opinion on eligibility of certain food and feed active substances for inclusion into Annex I

The SECR introduced the opinion and explained the approach followed.

A BPC member commented that information on the action that these substances have on harmful organisms was missing, which makes it difficult to assess if these substances are active substances as defined in the BPR. The SECR explained that only limited information on the uses of these substances was available in the notifications.

A BPC member noted that the list of substances assessed in this opinion was not consistent with the list published in the CA meeting paper CA-Sept16-Doc.5.3. The SECR explained that the opinion included only those substances of the list in the CA paper for which a compliant notification was received by ECHA.

With regard to the substances which are considered eligible for inclusion into Annex I, several question were raised by the BPC mainly concerning practical implications:

- For the powdered egg entry, it was agreed to consider the whole egg, the white and /or the yolk;
- For Saccharomyces *cerevisae* it was decided not to specify the strain. However, if used in biocidal products *Saccharomyces cerevisae* should fulfil the specifications according to the EU food law and/or plant protection products.
- When food grade specifications have been set for any of the substances listed, evidence of compliance with those specifications is considered sufficient to characterise the substance.

COM clarified the steps to be taken after adoption of the opinion:

- After receiving the opinion from ECHA, COM will discuss internally on how to proceed with a proposal to include these substances in Annex I. After that the CA meeting will discuss the delegated act to modify Annex I of the BPR.
- It was mentioned that for two notifciations, brandy and peanut butter, an appeal has been lodged (based on Article 17(6) of Regulation (EU) No 1062/2014) related to the decision by ECHA to consider the notification non-compliant according to Article 17(5) of Regulation (EU) No 1062/2014.
- For the substances which are not considered eligible in the opinion for inclusion in Annex I, the companies need to submit an application for approval or for inclusion into Annex I within two years after the ECHA acceptance of the notification, following the rules of the Review Regulation (EU) No 1062/2014.

  ECHA will publish the relevant information concerning the notifications with the appropriate deadlines and inform the notifiers.

The BPC opinion on eligibility of certain food and feed active substances for inclusion into Annex I was adopted by consensus.

Actions:

- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and forward the adopted opinion to COM by **12 January 2018**.

11. Any other business

Related to a question from one of the members related to the determination and assessment of relevant impurities, it was mentioned that there is some inconsistency among the evaluations performed by the eCAs due to the lack of agreed guidance on the relevant impurities. The Chairman suggested that guidance should be developed on relevant impurities and to possibly also include the establishment of the reference specifications covering the toxicological and ecotoxicological batches. In the meantime, an interim approach would need to be put in place until the guidance is agreed and available. The interim approach will be described in a document to be shared with and agreed by the BPC.

Actions:

- **SECR:** to provide a proposal for the next BPC on the assessment of relevant impurities with the aim to establish harmonised guidance.

12. 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 23rd meeting of BPC

11-14 December 2017

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
Item 2 - Agreement of the agenda	
The final draft agenda was agreed without changes.	**SECR:** to upload the agreed final agenda to the BPC CIRCABC IG as part of the draft meeting minutes after the meeting.
Item 4 - Agreement of the minutes and review of actions from BPC-22	
The revised version of the minutes of BPC-22 was agreed as proposed subject to several editorial modifications. SECR informed the meeting about the consequences of the criteria for ED (Regulation (EU) 2017/2100).	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website. **SECR:** to make the presentation on the ED criteria available via CIRCA BC.
Item 6 - Work programme for BPC	
6.1 Revised Work Programme 2017-2018 **6.2 Outlook for BPC**	
	Members: to send information on any further changes to the Work Programme (WP) to the SECR by **12 January 2018.** **SECR:** on the basis of the changes to update the WP on the ECHA website and in the BPC CIRCABC IG.
Item 7 - Applications for approval of active substances	
7.1 Templates and formats for active substance approval: 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 cholecalciferol for PT 14	
The BPC adopted by consensus the opinion for the approval of the active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **26 January 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 **12 January 2018** and publish it on the ECHA website.

7.3 Draft BPC opinion on formaldehyde for PT 2	
The BPC adopted by consensus the opinion for the approval of the active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **26 January 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 **12 January 2018** and publish it on the ECHA website..
7.4 Draft BPC opinion on empenthrin for PT 18	
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 **26 January 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 **12 January 2018** and publish it on the ECHA website..
7.5 Draft BPC opinion on cyphenothrin for PT 18	
The BPC adopted by consensus the opinion for the approval of the active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **26 January 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 **12 January 2018** and publish it on the ECHA website..
7.6 Draft BPC opinion on penflufen for PT 8	
The BPC adopted by consensus the opinion for the approval of the active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **26 January 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 **12 January 2018** and publish it on the ECHA website.

7.7. Outcome written procedure on the adoption of the BPC opinion on acetamiprid for PT 18	
The BPC agreed on the outcome of the written procedure on the adoption of the opinion and adopted the opinion by consensus.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **26 January 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 **12 January 2018** and publish it on the ECHA website.
7.8 Revised Assessment Report following the submission of data after active substance approval:	
7.8.1. MBIT for PT 6	
	Member (PL) to forward the revised assessment report to the SECR by **26 January 2018**
7.8.2. DCPP for PT 1, 2 and 4	
	Member (AT): to forward the revised assessment report to the SECR by **26 January 2018**.
7.8.3. CMK for PT 1, 2, 3, 6, 9 and 13	
	Member (FR): to forward the revised assessment report to the SECR by **26 January 2018**.
7.8.4. Cyfluthrin for PT 18	
	Member (DE): to forward the revised assessment report to the SECR by **26 January 2018**.
7.9 Question eCA (France) on the evaluation of carbon dioxide generated in-situ for PT 19	
The BPC agreed on the proposal prepared by the eCA (France)	
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 open a Newsgroup on BPC CIRCABC IG 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 opinions for the authorisation of the two applications for Union authorisation.	**Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by **11 January 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 **12 January 2018**. **SECR**: to forward the translated draft SPC to COM by **12 February 2018**.
Item 9 – Article 38 opinions	
9.1 Draft BPC opinion on unresolved objections during the mutual recognition of two insect repellents	
The BPC adopted by majority the opinion.	**Members** (FR and BE) to submit their minority opinion to SECR by **21 December 2017**. **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and forward the adopted opinion to COM by **12 January 2018**.
Item 10 – Article 75(1)(g) opinions	
10.1. Draft BPC opinion on inclusion into Annex I of corn cob	
The BPC adopted by majority the opinion.	**Members** (DE and SE) to submit their minority opinion to SECR by **21 December 2017**. **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and forward the adopted opinion to COM by **12 January 2018**.
10.2. Draft BPC opinion on copper sulphate pentahydrate – PT 3	
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 **12 January 2018**.
10.3 Draft BPC opinion on eligibility of certain food and feed active substances for inclusion into Annex I	
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 **12 January 2018**.
Item 11 – Any other business	
The BPC discussed the issue of the assessment of relevant impurities.	**SECR:** to provide a proposal for the next BPC on the assessment of relevant impurities with the aim to establish harmonised guidance.

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Part III - List of Attendees

Members	European Commission
BORGES Teresa (PT)	CHATELIN Ludovic (DG SANTE)
BROVKINA Julija (LV)	LAS HERAS Alfonso (DG SANTE)
CABALLO DIÉGUEZ Covadonga (ES)	**Advisers**
CEBASEK Petra (SI)	FRANK Ulrike (SE)
COSTIGAN Michael (UK)	HADAM Anna (PL)
DRAGOIU Simona (RO)	HÄMÄLÄINEN Anna-Maija (FI)
GIORDMAINA Wayne (MT)	JENSEN Pia Haugaard (DK)
GORDON Suzanne Collett (NO)	KALKERS Lucas (NL)
HAHLBECK Edda (SE)	KRETSCHMAR Ev (DE)
JÄGER Stefanie (DE)	LEPAGE Anne (BE)
KOIVISTO Sanna (FI)	PALOMÄKI Jaana (FI)
LANS Martine (NL)	STANG Christoph (DE)
LARSEN Jørgen (DK)	TIPPING Lee (UK)
MERISTE Anu (EE)	WEINHEIMER Viola (DE)
MIKOLASKOVA Denisa (SK)	**Accredited Stakeholder Observers**
RUSCONI Manuel	MIHAI Camelia (CEFIC)
VAN BERLO Boris (BE)	MONTMOREAU Bertrand (CEPA)
VRHOVAC FILIPOVIC Ivana (HR)	**ECHA Staff**
	ANTAL Diana
	ESTEVAN MARTINEZ Carmen
	GUTIERREZ ALONSO Simon
Alternate members	KURONEN Terhi
ALEXANDROS Gavriel (CY)	LOPEZ SERRANO Paloma
CARBERRY Stephen (IE)	MARQUES NOGUEIRO Eugenia
COLLET Romy (FR)	MULLER Gesine
HUSZAL Sylwester (PL)	PECORINI Chiara
MIKOLÃS Jan (CZ)	RODRIGUEZ UNAMUNO Virginia
PÜRGY Reinhild (AT)	SAEZ RIBAS Monica
SZENTGYÖRGYI Timea Ilona (HU)	SZYMANKIEWICZ Kasia
VAGIAS Vasileios (EL)	VAN DE PLASSCHE Erik

Applicants	Apologies
HOWARD Karen (EXPONENT) for cholecalciferol for PT 14	RUBBIANI Maristella (IT)
GARTLAND Kevan (SUMITOMO CHEMICAL (UK) PLC) for empenthrin for PT 18 and for cyphenothrin for PT 18	ZIGRAND Jeff (LU)
BICKERS Claudia (Lanxess Deutschland GmbH) for penflufen for PT 8	
DEMOMENT Isabelle (HYPRED SAS) for Union authorisation applications for product families containing iodine / PVP-iodine	
OLEDZKA Malgorzata (Ecolab) for Union authorisation applications for product families containing iodine / PVP-iodine	
VAN SLOUN Petra (Merck KGaA) for unresolved objections during the mutual recognition of two insect repellents	
VAN WYHE-STORGAARD Jan (Vitfoss) for copper sulphate pentahydrate for PT 3	
Experts accompanying applicants	
BROWN Laura-Anne, accompanying HOWARD Karen, for cholecalciferol for PT 14	
RENAULT-BILLAULT Dominique, accompanying HOWARD Karen, for cholecalciferol for PT 14	
GALLER Martina, accompanying BICKERS Claudia for penflufen for PT 8	
WAGNER Silvia, accompanying DEMOMENT Isabelle, for Union authorisation applications for product families containing iodine / PVP-iodine	
BRIEDEN Christian, accompanying OLEDZKA Malgorzata, for Union authorisation applications for product families containing 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-23

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-23 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2	BPC-A-23-2017_rev1	Draft agenda	
4	BPC-M-22-2017	Draft minutes from BPC-22	
5.2	BPC-23-2017-01	Administrative issues and report from the other Committees	
6.1	BPC-23-2017-02	BPC updated Work Programme 2017-2018	
6.2	BPC-23-2017-03	Outlook for the BPC	
7.1	BPC-23-2017-04	Templates and formats for active substance approval: catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval	
7.7	BPC-23-2017-10A	Outcome written procedure on the adoption of the BPC opinion on acetamiprid for PT 18	
8.2	BPC-23-2017-10B	Comments submitted by MS	
8.3	BPC-23-2017-10C	Revised opinion	
7.8		Revised Assessment Report following the submission of data after active substance approval:	
7.8.1	BPC-22-2017-11	MBIT for PT 6	
7.8.2	BPC-22-2017-12	DCPP for PT 1, 2 and 4	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.2	BPC-23-2017-05A	Cholecalciferol PT 14	Draft BPC opinion Draft BPC opinion with tc
	BPC-23-2017-05B		Assessment report
	BPC-23-2017-05C		Open issues
	BPC-23-2017-05D		Note from SE

7.3	BPC-23-2017-06A	Formaldehyde PT 2	Draft BPC opinion
	BPC-23-2017-06B1		Assessment report
	BPC-23-2017-06B2		Assessment report with tc
	BPC-23-2017-06C		Old Open issues
	BPC-23-2017-06D		Note from DE
	BPC-23-2017-06E		Open issues
7.4	BPC-23-2017-07A	Empenthrin PT 18	Draft BPC opinion
	BPC-23-2017-07B		Assessment report
	BPC-23-2017-07C		Open issues
7.5	BPC-23-2017-08A	Cyphenothrin PT 18	Draft BPC opinion
	BPC-23-2017-08B		Assessment report
	BPC-23-2017-08C		Open issues
7.6	BPC-23-2017-09A	Penflufen PT 8	Draft BPC opinion
	BPC-23-2017-09B		Assessment report
	BPC-23-2017-09C		Open issues
7.9	BPC-23-2017-22	Question eCA (France) on the evaluation of carbon dioxide generated in-situ for PT 19	
8.2	BPC-23-2017-13A	UA iodine: ECOLAB	Draft BPC opinion
	BPC-23-2017-13B1		Draft SPC
	BPC-23-2017-13B2		Draft SPC with tc
	BPC-23-2017-13C1		Draft PAR
	BPC-23-2017-13C2		PAR with tc
	BPC-23-2017-13C3		PAR conf annex
	BPC-23-2017-13D		Open issues
	BPC-23-2017-13E		Statement corrosiveness to metals
	BPC-23-2017-13F		Statement Ecolab
	BPC-23-2017-13G		Statement eCA
8.2	BPC-23-2017-14A	UA iodine: HYPRED	Draft BPC opinion
	BPC-23-2017-14B1		Draft SPC
	BPC-23-2017-14B2		Draft SPC with tc
	BPC-23-2017-14C1		Draft PAR
	BPC-23-2017-14C2		PAR with tc
	BPC-23-2017-14C3		PAR conf annex
	BPC-23-2017-14D		Open issues
	BPC-23-2017-14E		Statement corrosiveness to metals

9.1	BPC-23-2017-15A	Unresolved objections during the mutual recognition of two insect repellents	Draft BPC opinion
	BPC-23-2017-15B		Compiled comments
10.1	BPC-23-2017-16A	Inclusion into Annex I of corn cob	Draft BPC opinion
	BPC-23-2017-16B		Compiled comments
10.2	BPC-23-2017-17	Copper sulphate pentahydrate PT 3	Draft BPC opinion
10.3	BPC-23-2017-18	Eligibility of certain food and feed active substances for inclusion into Annex I	Draft BPC opinion

21 November 2017
BPC-A-23-2017_rev1

Draft agenda

23rd meeting of the Biocidal Products Committee (BPC)

11 – 14 December 2017

ECHA Conference Centre, Annankatu 18, Helsinki

Starts on 11 December at 13:30, ends on 14 December at 16:00

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-23-2017

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-22

BPC-M-22-2017

For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

BPC-23-2017-01

For information

6. – Work programme for BPC

6.1. Revised BPC Work Programme 2017-2018

BPC-23-2017-02

For information

6.2. Outlook for BPC

BPC-23-2017-03

For information

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

7.1. Templates and formats for active substance approval: catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval

BPC-23-2017-04

For information

7.2. Draft BPC opinion on cholecalciferol for PT 14

Previous discussion(s): WG-I-2017; BPC-21

BPC-23-2017-05A, B, C and D

For adoption

7.3. Draft BPC opinion on formaldehyde for PT 2

Previous discussion(s): TM-I-2012; (withdrawn from BPC-13)

BPC-23-2017-06A, B and C

For adoption

7.4. Draft BPC opinion on empenthrin for PT 18

Previous discussion(s): WG-IV-2017

BPC-23-2017-07A, B and C

For adoption

7.5. Draft BPC opinion on cyphenothrin for PT 18

Previous discussion(s): WG-II-2017; WG-III-2017

BPC-23-2017-08A, B and C

For adoption

7.6. Draft BPC opinion on penflufen for PT 8

Previous discussion(s): WG-IV-2017

BPC-23-2017-09A, B and C

For adoption

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

7.7. Outcome written procedure on the adoption of the BPC opinion on acetamiprid for PT 18

BPC-23-2017-10

For information

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

7.8.1. MBIT for PT 6

BPC-23-2017-11

For agreement

7.8.2. DCPP for PT 1, 2 and 4

BPC-23-2017-12

For agreement

7.8.3. CMK for PT 1, 2, 3, 6, 9 and 13

BPC-23-2017-19

For agreement

7.8.4. Cyfluthrin for PT 18

BPC-23-2017-21

For agreement

7.9. Question eCA (France) on the evaluation of carbon dioxide generated in-situ for PT 19

BPC-23-2017-22

For information

Item 8 – Union authorisation[‡]

8.1 Update on Union authorisation

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

BPC-23-2017-13A, B, C and D

For adoption

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

BPC-23-2017-14A, B, C and D

For adoption

Item 9 – Article 38 opinions

9.1 Draft BPC opinion on unresolved objections during the mutual recognition of two insect repellents

BPC-23-2017-15A and B

For adoption

Item 10 – Article 75(1)(g) opinions

10.1 Draft BPC opinion on inclusion into Annex I of corn cob

BPC-23-2017-16A and B

For adoption

10.2 Draft BPC opinion on copper sulphate pentahydrate – PT 3

BPC-23-2017-17

For adoption

10.3 Draft BPC opinion on eligibility of certain food and feed active substances for inclusion into Annex I

BPC-23-2017-18

For adoption

Item 11 – Any other business

Item 12 – Action points and conclusions

For agreement

Provisional time schedule for the

23rd meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Annankatu 18, Helsinki

11 December 2017: starts at 13:30; 14 December ends at 16:00

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.

Monday 11 December: afternoon session

Items 1-5	Opening items and administrative issues
Item 6	Work programme of the BPC 2017-18
Item 10.1	Draft BPC opinion on inclusion into Annex I of corn cob
Item 10.2	Draft BPC opinion on copper sulphate pentahydrate – PT 3
Item 7.9	Question eCA (France) on the evaluation of carbon dioxide generated in-situ for PT 19

Tuesday 12 December: morning session

Item 8.1	Update on Union authorisation
Item 8.2	Draft BPC opinion on Union authorisation applications for product families containing iodine / PVP-iodine

Tuesday 12 December: afternoon session

Item 8.2	Draft BPC opinion on Union authorisation applications for product families containing iodine / PVP-iodine (continued)
Item 9.1	Draft BPC opinion on unresolved objections during the mutual recognition of two insect repellents

Wednesday 13 December: morning session

Item 7.1	Templates and formats for active substance approval: catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval
Item 7.2	Draft BPC opinion on cholecalciferol for PT 14
Item 7.3	Draft BPC opinion on formaldehyde for PT 2

Wednesday 13 December: afternoon session

Item 7.4	Draft BPC opinion on empenthrin for PT 18
Item 7.5	Draft BPC opinion on cyphenothrin for PT 18

Thursday 14 December: morning session

Item 7.6	Draft BPC opinion on penflufen for PT 8
Item 7.7	Outcome written procedure on the adoption of the BPC opinion on acetamiprid for PT 18
Item 7.8	Revised Assessment Report following the submission of data after active substance approval:
Item 7.8.1	MBIT for PT 6
Item 7.8.2	DCPP for PT 1, 2 and 4
Item 7.8.3	CMK for PT 1, 2, 3, 6, 9 and 13
Item 7.8.4	Cyfluthrin for PT 18

Thursday 14 December: afternoon session

Item 10.3	Draft BPC opinion on eligibility of certain food and feed active substances for inclusion into Annex I
Item 11	AOB
Item 12	Action points and conclusions

End of meeting

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