

4 March 2020 BPC-M-33-2019

Minutes of the 33rd meeting of

the Biocidal Products Committee (BPC)

10-11 December 2019

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chairman of the Biocidal Products Committee (BPC) welcomed the participants to the 33rd BPC meeting.

Regarding the BPC membership, the Chairman stated that there is a new appointed BPC member from Belgium; Charlotte Brandt, and a new appointed alternate BPC member from Belgium as well; Hélène Jarrety. The Chairman also stated that currently there is no BPC member nor alternate member from Poland.

The Chairman then informed the BPC members of the participation of 27 members, including 5 alternates. In addition, Poland was represented by an invited expert.

5 advisers and 6 representatives from accredited stakeholder organisations (ASOs) were present at the meeting. Representatives from PETA and Aqua Europa, who were present for the first time, introduced their organisations to the meeting. A representative from the European Commission attended the meeting.

Applicants were invited and present for their specific substances under agenda item 7 where details are provided in the summary record of the discussion for the substances and in Part III of the minutes. Applicants were invited for their biocidal products under agenda item 8, but were not present at the meeting.

The Chairman stated that the United Kingdom was invited to this meeting, but sent their apologies. After the Brexit, which has been delayed to 31 January 2020, the UK is to be considered a third country and only following special agreements with the Executive Director of ECHA, with consent of the Commission, may UK representatives observe or participate in BPC meetings.

2. Agreement of the agenda

The Chairman introduced the final draft agenda (BPC-A-33-2019_rev2) and invited any additional items. No additional items were presented and the agenda was adopted. The final version of the agenda will be uploaded to the BPC CIRCABC IG as part of the meeting minutes.

The Chairman informed the meeting participants that the meeting would be recorded for the purpose of the minutes and that the recording would be deleted after the agreement of the minutes.

The Chairman informed the meeting why several agenda items dealing with post-approval data have been withdrawn from the agenda. The document "When to revise the List of Endpoints after post-approval data?" which was prepared following a request of the German CA, has also been withdrawn. ECHA explained that several legal issues had to be clarified first and that collaboration with the Coordination Group was needed to clarify: i) how to use new active substance data submitted during product authorisation; ii) how to use post-approval data submitted under section 2.5 of the BPC opinion. Until that time the BPC discussions on post-approval data submitted under section 2.5 of the BPC opinion are put on hold.

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-31

The revised draft minutes from BPC-31 (BPC-M-31-2019), incorporating the comments received, were agreed.

The Chairman noted that most of the actions from BPC-31 have been carried out:

- The following documents were finalised by the SECR and made available after the meeting: i) confidentiality claims for the manufacturing site; ii) consultation of BPRS on risk management measures (RMM); iii) guidance on relevant impurities; iv) guidance on storage stability: decision tree; v) note ECHA on submission of additional information and withdrawal (including letter templates); vi) reporting ED properties in the BPC opinion on an application for UA.
- After the document on the "Biocides assessment and RAC opinion on harmonised classification" was finalised and published the SECR has amended the working procedure on active substance approval stating that for active substances with a classification Muta Cat. 2 will require a RAC opinion before submission for peer review.

Following a question from one of the members the Chairman clarified that the guidance document on relevant impurities is not yet available on the ECHA web-site but only via the the CIRCA BC Interest Group of the BPC. This means that the guidance document is not yet applicable.

The Chairman further informed the meeting on the following:

- The Chairman noted that for the AOB of BPC-31 on "Risk assessment of the professional user combination of exposure from product use and dietary intakes" the member from DE informed the SECR that they will not prepare a revised document for the BPC.
- The Chairman informed the meeting on the processing of personal data in the dissemination of (Product) Assessment Reports, where ECHA requests that all the names of the study authors are blackened in the reference lists of both reports. A member and the Commission stated their disagreement with this request as there is no need to blacken all author names according to their interpretation of the General Data Protection Regulation. The SECR informed that their request is in line with the general ECHA policy on this issue, but stated that the request will not retroactively be applied: it is envisaged that this policy will be applied gradually.
- The Chairman informed that the applicant for the approval of metofluthrin for PT
 19 has withdrawn its application. Although the peer review was finalised and the
 BPC opinion agreed and awaiting the ED assessment for adoption, ECHA in

consultation with the Commission and the eCA UK agreed to accept the withdrawal. Main reason for accepting this late withdrawal was the fact that this is a new active substance so biocidal products containing metofluthrin for PT 19 are not available on the EU market.

- An e-consultation of the BPC members was launched on several issues raised at the ENV WG with the aim to discuss these issues at the first BPC in 2020.
- The BPRS meeting of 7–8 November discussed the document prepared by the SECR on RMM mentioned above, after it was distributed to the BPRS for written consultation. A limited number of comments was received. The main comment was that it was difficult to provide comments for the BPRS members without the context of the RMM and that many listed RMMs were too general to enable commenting. It was decided at the meeting that the SECR will provide a revised version of the document providing the context of the listed RMMs for a next consultation round. Consequently, this item will come back at the appropriate BPC meeting. In addition, the BPRS indicated they are open to ad-hoc consultation by the BPC.

Actions:

• **SECR:** to upload the agreed minutes from BPC-31 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

-

5.3 ECHA Activities Coordination Tool (ACT)

ECHA presented the ECHA Activities Coordination Tool (ACT) to the members. ECHA informed that this tool will be extended to cover biocides at some point, but the timing for this further development was not specified.

6. Work Programme for BPC

6.1 BPC Work Programme for active substance approval

6.2 BPC Work Programme for Union Authorisation

6.3 Outlook for the BPC

The Chairman informed members that the Work Programme for active substance approval was revised after the last BPC meeting. Members were invited to contact the SECR on possible changes on the revised programme after which an updated version will be published on the ECHA website.

The Chairman stated that:

- For active substance approval 9 opinions are adopted in 2019 of which 3 are for the Review Programme and 6 are returned opinions via Article 75(1)(g) for ED assessment.
- For Union authorisation the number of adopted opinions for 2019 is 11. The Chairman refered to agenda item 8.1 for a further discussion.
- The scheduled opinions for 2020 are indicated in both work programmes: currently 10 for the Review Programme; 2 active substance applications submitted under the BPR; 10 returned opinions via Article 75(1)(g) for ED assessment and 11 for Union authorisation.
- The SECR expressed its concerns with respect to the delays observed in the active substance approval and Union authorisation process.

The Chairman asked the eCAs being rapporteur for active substances or Union authorisations scheduled for discussion at the March 2020 BPC meeting (BPC-34), to confirm this planning to the SECR by 15 January 2020.

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 meeting to meeting. Progress must also be made on backlog reports submitted before 1st September 2013. Reference was also made to the discussions at the last CA meeting on the ECHA Action Plan on Active Substance Approval.

Actions:

• **Members**: to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by **20 December 2019**.

6.4 Status ED assessment for active substances

The SECR presented an overview on the status of the ED assessment of active substances. The document contains now also an overview of the consultations of the ED Expert Group. The Commission reiterated its request made at the last BPC meeting that the status report should cover all active substance dossiers under review, so that the progress on all dossiers on ED assessment is monitored and reported.

Actions:

• Members: to provide comments on the overview by 20 December 2019.

7. Applications for approval of active substances

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

The Chairman stated that this document had not been changed compared to the previous version.

7.1.2 Revised opinion template for active substance approval

The Chairman presented the document indicating the changes in Section 2.2.1, which now includes a reference to the appropriate guidance note agreed at the CA meeting on the ED assessment for active substances. The BPC agreed on the proposed changes.

Actions:

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

7.1.3 Opinion request Commission pursuant to Article 75(1)(g) on sodium chloride specifications and water quality for the generation of active chlorine by electrolysis

The SECR informed the meeting about the request received from the Commission. The BPC agreed that the member from the Slovak Republic will act as rapporteur. The intention is to adopt the opinion in the BPC meeting in June 2020 and to incorporate also the assessment of the endocrine disrupting properties.

7.2 Follow-up BPC opinion on DBNPA for PT 4 following BPC-31

After the adoption of the opinion at BPC-31 comments were received by the SECR that it did not adequately reflect the outcome of the discussions at the meeting. Following a written consultation the SECR prepared a proposal to amend the opinion as the majority of the members agreed with this observation. The proposal was agreed with some amendments for the conclusion for the section on the assessment for the environment.

The changes compared to the opinion adopted at BPC-31 relate to the identification of an exposure threshold and to the fact that there is currently no agreed methodology available for either undertaking a risk assessment based on ED properties (human health) or on how to consider the data used for the identification of whether this substance is an endocrine disruptor in the risk assessment (environment).

The BPC agreed on a proposal to amend the opinion adopted at BPC-31 for the approval of DBNPA in PT 4. The member from Portugal abstained.

Actions:

- **SECR**: to revise the opinion and carry out an editorial check in consultation with the rapporteur.
- **SECR**: to forward the amended adopted opinion to COM and publish it on the ECHA website.

7.3. Draft BPC opinion on icaridin for PT 19

The Chairman welcomed the applicant. The ASOs were allowed to be present during the discussion. The discussion focussed on the items included in the open issues table regarding the comments on the ED assessment and the draft BPC opinion.

The eCA introduced the dossier and indicated that the assessment of icaridin has already been discussed and agreed at the BPC-28 and then was returned to the eCA for the assessment of the ED properties. The assessment was revised by the eCA according to the conclusions of the Working Group (WG IV 2019). The WG concluded that it was not possible to conclude on the ED properties based on the information available. However, it was also noted that the available data show no indications of ED properties for human health. It was pointed out that the evaluation of icaridin for PT19 was submitted before 1 September 2013 therefore the BPC may conclude in its opinion that it is not possible to conclude on the ED properties of this active substance. It was confirmed by the Chairman that this was a back-log dossier.

With regard to one point in the open issues table on the testing strategy it was agreed that this should not be indicated in the assessment report due to the fact that data requirements may change before a dossier will need to be submitted for the renewal of icaridin.

Furthermore it was clarified by the Chairman and the COM that, as agreed in the CA meeting, the ED assessment on icaridin will not be completed at product authorisation stage, but will be completed at the renewal stage. The COM added that if there are data showing that the active substance has ED properties, the MSs can request an early review of the active substance.

The Commission remarked that it is indicated in section 2.5 of the draft opinion that some data are still missing after 10 years of examination, reminded that all data should normally be provided at the submission of applications, and strongly invited the applicant to provide the missing data without further delay. The Applicant indicated that these data are ready to be submitted.

All issues indicated in the open issues table were addressed and agreed.

The assessment report was agreed and the BPC opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 20 December 2019.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.

• **SECR:** to forward the adopted opinion to COM by 17 January 2020 and publish it on the ECHA website.

7.4 Draft BPC opinion on cyanamide for PT 3 and 18

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

The eCA indicated that cyanamide had already been discussed at BPC-16 where both opinions were adopted. At that time it was concluded that cyanamide fulfils the ED interim criteria being classified as carcinogenic category 2 and toxic for reproduction category 2. After entering into force of Regulation (EU) 2017/2100, after discussion with Member States Biocides Competent Authorities, the Commission returned the opinions to the Agency in April 2018 via an Article 75(1)(g) procedure and requested to include the assessment according to the criteria for endocrine disrupting (ED) properties. The ED assessment was disscussed at the ED EG and the Human Health and Environment Working Groups during 2019, both supporting the eCA conclusion that cyanamide is considered having endocrine disruptor properties with respect to human health and non-target organisms. Following a question by the Commission it was confirmed by the SECR and the eCA that the evaluation of ED properties was carried out in line with the existing guidance¹ following the agreed procedures, and that the conclusions were correctly reflected in the draft assessment report. The conclusions were also supported by WG members.

The applicant maintained its opinion and provided the following statement: "the assessment is incomplete and has only partly been performed in accordance with the ED Guidance document. Relevant criteria of the ED Guidance are not fulfilled. Based on the incomplete assessment lacking consideration of all the evidence (positive and negative) a conclusion on the ED properties of cyanamide cannot be drawn. A full assessment according to the ED Guidance Document was provided by the applicant indicating that further information is needed for a scientifically reliable conclusion. The eCA has revised the ED assessment for cyanamide several times to consider comments made during the commenting period, the ED Expert Group and WGs discussions. However, many comments to which the eCA agreed to are not reflected in the updated versions. The requested amendments were only partly considered even in the last update of the draft CAR as provided by the eCA before the BPC-33."

For cyanamide, the results from both public consultations resulted in similar contributions which are mainly supporting the use of cyanamide and providing analysis of possible economical impacts of its absence in pig farming. In addition, the eCA investigated the already approved active substances for both PTs and whether they might be an alternative for the uses assessed for cyanamide. Subsequently, it was not possible for the eCA to perform an assessment for possible alternatives. Two BPC members informed that in their Member States cyanamide is not used and the manure is not treated: pig stables are cleaned and disinfected (alternative for PT 3) and a biological means is used by releasing a different type of fly into the stables which predates on the fly larvae in the manure (alternative for PT 18). These alternative strategies will be included in the opinions.

¹ Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009.

Another BPC member informed that they do not have products containing cyanamide authorised on their market.

The BPC held a general discussion on the section in the opinion on identification of potential alternatives or technologies (including the results of the public consultation). As requested several times and agreed in the CA meeting in 2016, the Commission asked the BPC members to have a more active role in finding possible alternatives by investigating their markets and thereby participate in the public consultation. The eCA mentioned that: i) the information submitted in the public consultation is almost always very limited; ii) availability but especially suitability of an alternative is difficult to assess; iii) already approved active substances were approved with substantial temporal differences (many have been approved under Directive 98/8/EC where e.g. the exclusion and substitution criteria did not exist) and for almost all ED properties have not been assessed; iv) existing alternatives might also still be in the evaluation process within the Review Programme; and v) many Member States do do not have detailed information on biocidal products marketable under transitional rules. The Commission highlighted that the input from the BPC members is not limited to what comes from the public consultation, but BPC members with their national colleagues shall develop and bring their own expertise about the use of biocides in their markets. This is important in order that the objective of the legislation to no longer use active substances highly hazardous is met.

The member from Denmark did not support the approval of the substance for PT 3 nor 18 based on the fact that it has endocrine disrupter properties and that according to national information there are alternatives available.

The remaining issues indicated in the open issues table were agreed. The assessment reports were agreed and the BPC opinions for PT 3 and PT 18 were adopted by majority.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 20 December 2019.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- Member (DK): to submit the minority position by 17 December 2019.
- **SECR:** to forward the adopted opinion to COM by 17 January 2020 and publish it on the ECHA website.

7.5 Draft BPC opinion on formaldehyde for PT 2 and 3

The Chairman welcomed the applicant. The ASOs were allowed to be present during the discussion. The discussion focussed on the items included in the open issues table regarding the comments on the assessment report and the draft BPC opinion.

The eCA indicated that formaldehyde for PT 2 and PT 3 has already been discussed at BPC-23 and BPC-13 respectively. Opinions were adopted in 2017 for PT2 and 2015 for PT3. Similar to cyanamide, the Commission returned the opinions to the Agency in April 2018 via an Article 75(1)(g) procedure and requested to include the assessment according to the criteria for endocrine disrupting properties. Formaldehyde already meets the exclusion criteria for being carcinogenic 1B.

The data submitted by the applicant would not allow to draw a conclusion. For reports submitted before 1 September 2013, it is mentioned in the relevant guidance note adopted at the CA meeting that the eCA has to conclude based on the already available data and/or the data provided by the applicant and, in case the data is insufficient to reach a conclusion, the BPC may conclude in its opinion that no conclusion could be drawn. It was noted that the evaluations of formaldehyde for PT 2 and PT 3 were submitted before 1 September 2013. Subsequently, the BPC concluded that no conclusion can be drawn whether formaldehyde fulfils criterion (d) of Article 5(1) and/or criterion (e) of Article 10(1).

Regarding alternatives, the information on approved active substances for the same PT had been updated compared to the already adopted opinions. The Commission asked again the BPC members to have a more active role in finding possible alternatives by investigating their markets and thereby providing information, and indicated to not be satisfied with the level of input provided by the BPC on the matter in its opinions.

All the issues indicated in the open issues table were agreed. The assessment reports were agreed and the BPC opinions for PT 2 and PT 3 were adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 20 December 2019.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion to COM by 17 January 2020 and publish it on the ECHA website.

7.6 Draft BPC opinion on carbendazim for PT 7 and 10

The Chairman welcomed the applicant. The ASOs were allowed to be present during the discussion. The discussion focussed on the items included in the open issues table regarding the comments on the assessment report and the draft BPC opinion.

The eCA indicated that carbendazim had already been discussed at BPC-25 and the opinions were adopted in April 2018. Similar to cyanamide and formaldehyde, the Commission returned the opinions to the Agency in June 2018 via an Article 75(1)(g) procedure and requested to include the assessment according to the criteria for endocrine disrupting (ED) properties. Carbendazim already meets the exclusion criteria for being carcinogenic 1B and toxic for reproduction 1B.

The data submitted by the applicant would not allow to draw a conclusion. For reports submitted before 1 September 2013, it is mentioned in the relevant guidance note adopted at the CA meeting that the eCA has to conclude based on the already available data and/or the data provided by the applicant and, in case the data is insufficient to reach a conclusion, the BPC may conclude in its opinion that no conclusion could be drawn. It was noted that the evaluations of formaldehyde for PT 2 and PT 3 were submitted before 1 September 2013. Subsequently, the BPC concluded that no conclusion can be drawn whether carbendazim fulfils criterion (d) of Article 5(1) and/or criterion (e) of Article 10(1).

Regarding alternatives, the information on approved active substances for the same PT had been updated compared to the already adopted opinions. The Commission asked again

the BPC members to have a more active role in finding possible alternatives by investigating their markets and thereby providing information, and indicated to not be satisfied with the level of input provided by the BPC on the matter in its opinions.

The member from SE stated that their opinion remains that the use of carbedazim in treated articles should be restricted due to its hazardous properties meeting the exclusion criteria and the unacceptable risks to the environment. The member from SE also noted that treated articles containing carbendazim can be imported to the EU market from third countries and that even if a Member State does not authorise a biocidal product containg carbendazim (considering none of the conditions of Article 5(2) is met) treated articles can be traded between Member States.

All the issues indicated in the open issues table were agreed. The assessment reports were agreed and the BPC opinions for PT 7 and PT 10 were adopted by majority.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 20 December 2019.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- Member (SE): to submit the minority position by 17 December 2019.
- **SECR:** to forward the adopted opinion to COM by 17 January 2020 and publish it on the ECHA website.

8. Union authorisation

8.1 Update on Union authorisation

An update on Union authorisation was given by the SECR: i) an overview of the current status of the UA-APP and UA-BBP applications in ECHA's pipeline; ii) procedural issues; iii) on-going coordination activities by ECHA on coordination of the Union authorisation process; iv) SPC linguistic check process.

i) From the table on on-going applications it can be concluded that there are substantial delays in processing UA applications: applications that were submitted in 2015 and 2016 should already have been finalised. This also has an effect on the UA-BBP cases as no decision can be taken on these when the UA-APP cases are still ongoing.

ii) The first two rejections by eCAs for UA-APP cases have been recorded due to failing the validation because of missing information. eCAs are encouraged to contact ECHA before taking the decision to reject. The working procedure will be amended accordingly.

Comparative assessment reports for UA-APP cases should be uploaded in the specific CIRCA BC folder for comparative assessment reports and should be send together with the PAR. The working procedure will be amended accordingly.

Co-formulants should be reported in UA-APP dossiers as in NA-APP dossiers and therefore, in accordance with REACH, the technical content should be reported in the SPC and PAR

(in contrast to the active substance where additionally the "pure" content should be reported in the PAR²).

iii) In general Member States are encouraged to contact ECHA to bring forward improvement proposals on the working procedures. Member States are also encouraged to contact ECHA's dossier managers pro-actively on the progress of the dossiers they are working on. Last, Member States were encouraged to take into consideration the timelines within which the SPC translations should be checked as late procedures will lead to delays in the decision making process of the Commission. It is known that applicants sometimes supply inadequate translations. Industry representatives were asked to inform their members to improve the translations. Member States were asked to pay particular attention to the quality of the translations as well.

iv) Progress of the linguistic checks by the Member States were presented for the 11 UA-APP cases that have been launched so far. Member States were asked to check their internal procedures and improve on adherence to the deadlines.

Finally it was pointed out that the email address of the UA functional mailbox has changed to: <u>biocides-union-authorisation@echa.europa.eu</u>.

The Commission expressed concerns on the delays in the processing of the applications for UA. In particular, some applications submitted in 2015 and 2016 are still under evaluation. Member States were asked to contact ECHA if support is needed. The Commission also stressed the importance of the quality of the translations of the SPC and that checks have to be made by Member States to avoid complications during the decision-making process or the need of corrigenda of decisions afterwards.

Actions:

• **SECR:** to upload the presentation on the BPC CIRCABC IG.

8.1.1 Revised opinion template for Union authorisation

The Chairman presented the document indicating the changes presented on the first page of the document. The main changes relate to the introduction of post-authorisation conditions and the situation when concerns are identified for co-formulants potentially meeting the criteria for an endocrine disruptor where a REACH process is triggered. The BPC agreed on the proposal.

Actions:

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

² See Q&A 10 in "Q&A concerning the content of some SPC sections" (CA-May15-Doc.4.4-Final.rev4; updated as per CA-Nov18-Doc.4.8.rev1).

8.1.2 Introducing new data during the peer review phase for applications for Union authorisation

The Chairman introduced the document which was prepared by the SECR to harmonise the approach between eCAs. It was noted by the Chairman that the same principles are applied as in an already existing document on the same issue for the active substance approval process. The members welcomed the document stating however that the only reason to introduce new information is that "information initially considered acceptable by the eCA, but considered of insufficient quality or not adequate by the commenting MSCAs during the peer review process". It was agreed to remove the other reason mentioned in the document. With respect to the conditions under which it can be accepted that new information is introduced during peer review, it was agreed to add that in justified cases it can be accepted to deviate from the principles listed, provided the 180 days time limit must be adhered to. Some other comments were made by the members, which will be incorporated. The BPC agreed on the document which will be made available on the BPC web-page of the ECHA website.

Actions:

• **SECR**: to revise the document incorporating the discussion at the BPC and publish it on BPC CIRCABC IG and the ECHA website.

8.1.3 Implementation of CA document on "Addressing concerns of coformulants that contribute significantly to a product's efficacy" (CA-Jan18-Doc.4.2_final)

The Chairman introduced the document and stated that this document was agreed at a CA meeting in 2018 which means it will be applicable from January 2020 onwards. The Chairman indicated that the document was on the agenda to inform the members that ECHA will consider this in its accordance check for Union authorisation applications from this date onward and expects that eCAs will take this into consideration for UA applications. The Chairman indicated that there is already some experience within the Efficacy WG. One member mentioned that there is a gap in the document related to co-formulants known as active substances, which were not approved during the review process. COM explained that the CA document covers all situations and in such case, as in all other cases, as a first step a justification that the substance acts as co-formulant is needed.

8.1.4 Revised procedure "Linguistic review of the translations of the summary of product characteristics (SPC) for Union authorisation applications

SECR presented a new procedure for the linguistic check of the SPC translations, aimed at having the linguistic review of the SPCs only after the vote in the Standing Committee meeting. A member suggested several improvements for the document, mainly aimed at clarifying what to do with SPCs that are completely inadequate and for SPCs that do not require any further improvement. ECHA promised to take over the suggestions. The BPC agreed on the document with the proposed amendments. The procedure published on the BPC web-site will be updated accordingly.

The suggestions on improvement were not on the changes proposed in this version of the document, however, ECHA indicated that improvement suggestions for any working procedure were always welcome. BPC members were encouraged to pro-actively contact ECHA for improvement suggestions and not to wait for a certain document to be tabled for the BPC meeting. One member mentioned that the conversion of the XML version of the SPC to a Word version in the SPC editor leads to the disappearance of the formulation type. ECHA mentioned that this will be forwarded to the IT colleagues.

Actions:

• **SECR**: to revise the document incorporating the discussion at the BPC and publish it on BPC CIRCABC IG and the ECHA website.

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

The Chairman informed that the applicant did not participate for this agenda item. The ASOs were not allowed to be present during the discussion. The discussion focussed on the items included in the open issues table.

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

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 20 December 2019.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by 17 January 2020.

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

The applicant was not present but did not object to the presence of ASOs during the discussion. The discussion focussed on the items included in the open issues table.

It was agreed that the information regarding the packaging stability will be requested at renewal stage and a related statement will be included in the BPC opinion.

The relevant guidance on ED assessment of co-formulants and the REACH process are now available. Therefore the members agreed that the REACH process should be triggered by the eCA by notifying the relevant co-formulants where a concern was identified in the PAR with respect to their ED properties. This will be indicated in the BPC opinion.

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

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

Actions:

- **Rapporteur:** to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by 20 December 2019.
- **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinion, draft SPC and final PAR to COM by 17 January 2020.

9. Any Other Business

9.1 Introduction of ECHA Read-across assessment framework in biocides

The SECR presented the document on introduction of ECHA Read-Across Assessment Framework (RAAF) to biocides assessment. The initiative was welcomed and supported by the members as it is expected that RAAF will ensure more harmonised, transparent and systematic assessment of the read-across cases. Notably the RAAF will support creating a clear explanation on why a certain read-across case was accepted or rejected. However, flexibility was requested when applying the methodology and especially in the first cases where RAAF is followed the consequences should be carefully considered. It was therefore decided to start first with a testing phase to gain experience and to find out if and where biocide specific instructions would be needed. For instance, a practical guide to address biocide specific issues could be created once feedback has been collected from using RAAF in biocide assessment. For the environment part, a first version of a reporting template has been created and it is expected that similar documentation will be provided for the human health assessment. Specific timelines for the testing phase or for the follow-up actions have not yet been agreed but the members were encouraged to start using the RAAF. SECR will inform the Human Health and Environment Working Groups when more information is available.

9.2 Request to ECHA on guidance for risk assessment for bees

The SECR informed that an Article 75(1)(g) request was received from the Commission and asked the BPC members to consider and inform ECHA if their Member State Competent Authority would like to be involved in developing the guidance.

10. Agreement of the action points and conclusions

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

Part II - Main conclusions and action points

Agreed at the 33rdmeeting of BPC

10-11 December 2019

Agenda point		
Conclusions / decisions / minority positions	Action requested after the meeting (by whom/by when)	
Item 2 - Agreement of the agenda		
The final draft agenda was <u>agreed</u> 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	v of actions from BPC-31	
The revised version of the minutes of BPC-31 was agreed as proposed. SECR: to upload the agreed minutes to the CIRCABC IG and to the ECHA website.		
Item 5 – Administrative issues		
-	-	
Item 6 - Work programme for BPC		
6.1 BPC Work Programme 2019-2020 for active substance approval		
6.2 BPC Work Programme 2019-2020 for U	nion authorisation	
-	Members: to send information on any further changes to the Work Programme (WP) for active substance approval to the SECR by 20 December 2019 .	
6.3 Outlook for BPC		
-	-	
6.4 Status ED assessment for active substa	nces	
-	Members: to provide comments on the overview by 20 December 2019	

Item 7 - Applications for approval of active su	bstances
7.1 Procedural and administrative aspects	
7.1.1 Catalogue of specific conditions and ele authorisation stage for active substance	ments to be taken into account at the product e approval
The BPC took note of the document.	-
7.1.2 Revised opinion template for active sub	stance approval
The BPC agreed on the proposal.	SECR : to revise the document and publish it on BPC CIRCABC IG.
7.1.3 Opinion request Commission pursual specifications and water quality for the generation of the ge	nt to Article 75(1)(g) on sodium chloride ation of active chlorine by electrolysis
The BPC agreed that the member from SK will act as the rapporteur for the request.	-
7.2 Follow-up BPC opinion on DBNPA for PT 4	following BPC-31
The BPC <u>agreed</u> on the proposal to amend the opinion adopted at BPC-31 for the approval of the	SECR: to revise the opinion and carry out an editorial check in consultation with the rapporteur.
active substance PT combination.	SECR: to forward the amended adopted opinion to COM and publish it on the ECHA website.
7.3 Draft BPC opinion on icaridin for PT 19	
The BPC <u>adopted by consensus</u> 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 20 December 2019 .
	SECR: to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
	SECR: to forward the adopted opinion to COM by 17 January 2020 and publish it on the ECHA website.
7.4 Draft BPC opinion on cyanamide for PT	3 and 18
The BPC <u>adopted by majority</u> the opinions for the approval of the active substance PT combination.	Rapporteur: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 20 December 2019 .
	SECR: to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
	Member (DK): to submit the minority position by 17 December 2019 .
	SECR: to forward the adopted opinion to COM by 17 January 2020 and publish it on the ECHA website.

7.5 Draft BPC opinion on formaldehyde for	DT 2 and 2
. ,	
The BPC <u>adopted by consensus</u> the opinions for the approval of the active substance PT combination.	Rapporteur : to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 20 December 2019 .
	SECR: to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur
	SECR: to forward the adopted opinion to COM by 17 January 2020 and publish it on the ECHA website.
7.6 Draft BPC opinion on carbendazim for P	T 7 and 10
The BPC <u>adopted by majority</u> the opinions for the approval of the active substance PT combination.	Rapporteur: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 20 December 2019 .
	SECR: to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur
	Member (SE): to submit the minority position by 17 December 2019.
	SECR: to forward the adopted opinion to COM by 17 January 2020 and publish it on the ECHA website.
Item 8 – Union authorisation	
8.1 Update on Union authorisation	
8.1.1 Revised opinion template for Union aut	horisation
The BPC agreed on the proposal.	SECR : to revise the document and publish it on BPC CIRCABC IG.
8.1.2 Introducing new data during the peer reaction	eview phase for applications for Union
The BPC <u>agreed</u> on the proposal described in the document.	SECR : to revise the document incorporating the discussion at the BPC and publish it on BPC CIRCABC IG and the ECHA website.
8.1.3 Implementation of CA document on "Ac contribute significantly to a product's efficacy	•
The BPC was informed about the document which will be applied from the beginning of 2020 onwards.	-

8.1.4 Revised procedure "Linguistic review of characteristics (SPC) for Union authoris			
Some modifications were proposed by the BPC to the revised procedure. The BPC agreed on the document.	SECR : to revise the document incorporating the discussion at the BPC and publish it on BPC CIRCABC IG and the ECHA website.		
8.2 Draft BPC opinions on Union authorisati containing propan-2-ol	on applications for a product family		
The BPC <u>adopted by consensus</u> the opinion for the authorisation of an application for Union authorisation.	Rapporteur: to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by 20 December 2019 .		
	SECR: to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.		
	SECR: to forward the adopted opinion, draft SPC and final PAR to COM by 17 January 2020 .		
8.3 Draft BPC opinions on Union authorisati containing iodine / PVP-iodine	8.3 Draft BPC opinions on Union authorisation applications for a product family		
The BPC <u>adopted by consensus</u> the opinion for the authorisation of an application for Union authorisation.	Rapporteur: to revise the product assessment report (PAR) and draft SPC in accordance with the discussions in the BPC and submit to the SECR by 20 December 2019 .		
	SECR: to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.		
	SECR: to forward the adopted opinion, draft SPC and final PAR to COM by 17 January 2020 .		
Item 9 –Any other business			
9.1 Applying the ECHA Read-Across Assessme	nt Framework in biocides		
The BPC discussed the document and agreed on the application of the framework as described in the document.	-		
9.2 Request to ECHA on guidance for risk assessment for bees			
The BPC was informed about the request from the Commission to develop this guidance document.	-		

oOo

Members **European Commission** BALDASSARRI Lucilla (IT) CHATELIN Ludovic (DG SANTE) BORGES Teresa (PT) GKINIS Georgios (DG SANTE) BRANDT Charlotte (BE) BROVKINA Julija (LV) **Advisers** CARBERRY Stephen (IE) EHNI Markus (DE) CEBASEK Petra (SI) **GEWERT Berit (SE)** COLLET Romy (FR) GUENNEWIG Kathrin (DE) DRAGOIU Simona (RO) HAMALAINEN Anna-Maija (FI) GAVRIEL Alexandros (CY) OOSTERWOUD Marieke (DE) GONZALEZ MARQUEZ Maria Luisa (ES) VAN DER MEER Cindy (NL) GREGERSEN Nina Falk (DK) HAHLBECK Edda (SE) **Invited experts** HAKAITE Palmira (LT) HUSZAL Sylwester (PL) JAGER Stefanie (DE) KOIVISTO Sanna (FI) Accredited Stakeholder Observers MERISTE Anu (EE) CINGOTTI Natacha (HEAL) MIKOLAS Jan (CZ) DREVE Simina (FECC) MIKOLASKOVA Denisa (SK) DROHMANN Dieter (Aqua Europa) PUERGY Reinhild (AT) MIHAI Camelia (CEFIC) RANDALL Marit (NO) PROCHAZKA Erik (PETA) SZANTO Emese (HU) VAN BERLO Boris (CEFIC) VAGIAS Vasileios (EL) VRHOVAC FILIPOVIC Ivana (HR) ECHA Staff ZIGRAND Jeff (LU) **AIRAKSINEN Antero** ESTEVAN MARTINEZ Carmen Alternate members JANKA Adel KALKERS Lucas (NL) **KENIGSWALD Hugues** MALLIA Lothar Paul (MT) **KURONEN** Terhi PYTHON François (CH) LAITINEN Jaana PRIHA Outi SAEZ RIBAS Monica SZYMANKIEWICZ Katarzyna

Part III - List of Attendees

	VAN DE PLASSCHE Erik
	VAN DER LINDEN Sander
	VAN GALEN Joost
Applicants	Apologies
Saltigo GmbH	UK
AlzChem AG	
Theseo	
EWABO Chemikalien GmbH & Co.	
Interhygiene GmbH	
Troy Chemical Company BV	

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-33

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-33 meeting

Meeting documents			
Agenda Point	Number	Title	
2	BPC-A-33- 2019_rev2	Draft agenda	
4	BPC-M-31-2019	Draft minutes from BPC-31	
5.2	-	Administrative issues and report from the other Committees	
5.3	-	ECHA Activities Coordination Tool (ACT)	
6.1	BPC-33-2019-01	BPC Work Programme for active substance approval	
6.2	BPC-33-2019-02	BPC Work Programme for Union Authorisation	
6.3	BPC-33-2019-03	Outlook for the BPC	
6.4	BPC-33-2019-04	Status ED assessment for active substances	
6.6	BPC-31-2019-09	Follow-up Active Substance Workshop 12-13 February 2019: Note ECHA on requesting additional information during the evaluation phase	
	Procedural and administrative aspects:		
	BPC-33-2019-05	7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval	
7.1	BPC-33-2019-06	7.1.2. Revised opinion template for active substance approval	
	BPC-33-2019-07	 7.1.3. Opinion request Commission pursuant to Article 75(1)(g) on sodium chloride specifications and water quality for the generation of active chlorine by electrolysis 	
	Update on Union authorisation		
	BPC-33-2019-19	8.1.1 Revised opinion template for Union authorisation	
8.1	BPC-33-2019-20	8.1.2 Introducing new data during the peer review phase for applications for Union authorisation	
	BPC-33-2019-21	8.1.3 Implementation of CA document on "Addressing concerns of co-formulants that contribute significantly to a product's efficacy" (CA-Jan18-Doc.4.2_final)	
	BPC-33-2019-22	8.1.4 Revised procedure "Linguistic review of the translations of the summary of product characteristics (SPC) for Union authorisation applications	

	BPC-33-2019-25A	Introduction of ECHA Read-across assessment framework in biocides		
9.1	BPC-33-2019-25B	Applying RAAF to biocides - additional document		
	BPC-33-2019-26A	Request to ECHA on guidance for risk assessment for bees Mandate to ECHA on bees		
9.2	BPC-33-2019-26B			
Substan	ce documents			
Agenda Point	Number	Substance-PT Title		
7.2	BPC-33-2019-08A	DBNPA for PT 4	Follow-up BPC opinion on DBNPA for PT 4 following BPC-31	
	BPC-33-2019-08B		Follow-up BPC opinion DBNPA_Proposal revision DE	
	BPC-33-2019-09A		Draft BPC opinion	
7.3	BPC-33-2019-09B	Icaridin PT 19	Assessment report	
	BPC-33-2019-09C		Open issues	
	BPC-33-2019-10A		Draft BPC opinion	
	BPC-33-2019-10B	Cyanamide PT 3	Assessment report	
7.4	BPC-33-2019-10C		Open issues	
7.4	BPC-33-2019-11A	Cyanamide PT 18	Draft BPC opinion	
	BPC-33-2019-10B		Assessment report	
	BPC-33-2019-10C		Open issues	
	BPC-33-2019-12A	Formaldehyde PT 2	Draft BPC opinion	
	BPC-33-2019-12B		Assessment report	
7.5	BPC-33-2019-12C		Open issues	
7.5	BPC-33-2019-13A	Formaldehyde PT 3	Draft BPC opinion	
	BPC-33-2019-13B		Assessment report	
	BPC-33-2019-12C		Open issues	
	BPC-33-2019-14A		Draft BPC opinion	
	BPC-33-2019-14B	Carbendazim PT 7	Assessment report	
7.6	BPC-33-2019-14C		Open issues	
7.0	BPC-33-2019-15A		Draft BPC opinion	
	BPC-33-2019-14B	Carbendazim PT 10	Assessment report	
	BPC-33-2019-14C		Open issues	
	BPC-33-2019-23A		Draft BPC opinion	
	BPC-33-2019-23B	UA: product family	SPC	
8.2	BPC-33-2019-23C	containing propan-2-ol	PAR	
	BPC-33-2019-23C1		Conf annex to PAR	
	BPC-33-2019-23D		Open issues	

	BPC-33-2019-23E		Note from eCA
	BPC-33-2019-24A	UA: product family	Draft BPC opinion
	BPC-33-2019-24B		SPC
8.3	BPC-33-2019-24C	containing iodine/PVP- iodine	PAR
	BPC-33-2019-24C1		Conf annex to PAR
	BPC-33-2019-24D		Open issues



04 December 2019 BPC-A-33-2019_rev2

Draft agenda 33rd meeting of the Biocidal Products Committee (BPC) 10 - 11 December 2019 ECHA Conference Centre, Annankatu 18, Helsinki Starts on 10 December at 09:30, ends on 11 December at 18:00

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-33-2019_rev2 For agreement

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

4. – Agreement of the minutes and review of actions from BPC-31

BPC-M-31-2019 For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

For information

5.3. ECHA Activities Coordination Tool (ACT)

For information

6. – Work programme for BPC

6.1.	1. BPC Work Programme for active substance approval		
		BPC-33-2019-01	
		For information	
6.2.	BPC Work Programme for Union authorisation		
		BPC-33-2019-02	
		For information	
6.3.	Outlook for BPC		
		BPC-33-2019-03	
		For information	
6.4.	Status ED assessment for active substances		
		BPC-33-2019-04	
		For information	

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

- 7.1. Procedural and administrative aspects:
 - 7.1.1. Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval

BPC-33-2019-05 *For information*

7.1.2. Revised opinion template for active substance approval

BPC-33-2019-06 For agreement

7.1.3. Opinion request Commission pursuant to Article 75(1)(g) on sodium chloride specifications and water quality for the generation of active chlorine by electrolysis

BPC-33-2019-07 For information

7.2. Follow-up BPC opinion on DBNPA for PT 4 following BPC-31 BPC-33-2019-08A,B *For agreement*

7.3. Draft BPC opinion on icaridin for PT 19

[‡] 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).

Previous discussion: BPC-28

BPC-33-2019-09A, B, C *For adoption*

7.4. Draft BPC opinion on cyanamide for PT 3 and 18

Previous discussion: BPC-16

PT 3: BPC-33-2019-10A, B, C PT 18: BPC-33-2019-11A and BPC-33-2019-10B, C *For adoption*

7.5. Draft BPC opinion on formaldehyde for PT 2 and 3 Previous discussion: BPC-13 PT 2: BPC-33-2019-12A, B

PT 2: BPC-33-2019-12A, B, C PT 3: BPC-33-2019-13A, B, C *For adoption*

7.6. Draft BPC opinion on carbendazim for PT 7 and 10 Previous discussion: BPC-25 PT 7: BPC-33-2019-144 B

PT 7: BPC-33-2019-14A, B, C PT 10: BPC-33-2019-15A and BPC-33-2019-14 B, C *For adoption*

8. – Union authorisation**

8.1 Update on Union authorisation

For information

8.1.1 Revised opinion template for Union authorisation

BPC-33-2019-19 For agreement

8.1.2 Introducing new data during the peer review phase for applications for Union authorisation

BPC-33-2019-20 For agreement

8.1.3 Implementation of CA document on "Addressing concerns of co-formulants that contribute significantly to a product's efficacy" (CA-Jan18-Doc.4.2_final)

BPC-33-2019-21 For discussion

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

8.1.4 Revised procedure "Linguistic review of the translations of the summary of product characteristics (SPC) for Union authorisation applications

BPC-33-2019-22 *For agreement*

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

Previous discussion: WG-IV-2019

BPC-33-2019-23A, B, C, C1, D, E *For adoption*

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

Previous discussion: WG-IV-2019

BPC-33-2019-24A, B, C, D For adoption

9. - Any other business

9.1 Applying the ECHA Read-Across Assessment Framework in biocides BPC-33-2019-25A, B

For agreement

9.2 Request to ECHA on guidance for risk assessment for bees

BPC-33-2019-26A, B For information

10. - Action points and conclusions

For agreement



Provisional time schedule for the 33rd meeting of the Biocidal Products Committee (BPC) ECHA Conference Centre, Annankatu 18, Helsinki 10 December 2019: starts at 09:30; 11 December 2019 ends at 18:00

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 10 December: morning session

Items 1-5	Opening items and administrative issues		
Item 5.3	ECHA Activities Coordination Tool (ACT)		
Item 6	Work programme for BPC		
	6.1.	BPC Work Programme for active substance approval	
	6.2.	BPC Work Programme for Union authorisationl	
	6.3.	Outlook for BPC	
	6.4.	Status ED assessment for active substances	
Item 7.1	7.1 Procedural and administrative aspects:		
	7.1.1.	Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval	
	7.1.2.	Revised opinion template for active substance approval	
	7.1.3.	Opinion request Commission pursuant to Article 75(1)(g) on sodium chloride specifications and water quality for the generation of active chlorine by electrolysis	
Item 7.2	Follow-up BPC opinion on DBNPA for PT 4 following BPC-31		
Item 7.3	Draft BP	PC opinion on icaridin for PT 19	

Tuesday 10 December: afternoon session

- Item 7.4 Draft BPC opinion on cyanamid for PT 3 and 18
- Item 7.5 Draft BPC opinion on formaldehyde for PT 2 and 3
- Item 7.6 Draft BPC opinion on carbendazim for PT 7 and 10
- Item 8.1 Update on Union authorisation
 - 8.1.1. Revised opinion template for Union authorisation
 - 8.1.2. Introducing new data during the peer review phase for applications for Union authorisation
 - 8.1.3. Implementation of CA document on "Addressing concerns of co-formulants that contribute significantly to a product's efficacy" (CA-Jan18-Doc.4.2_final)
 - 8.1.4. Revised procedure "Linguistic review of the translations of the summary of product characteristics (SPC) for Union authorisation applications

Wednesday 11 December: morning session

- Item 8.2Draft BPC opinions on Union authorisation applications for a product
family containing propan-2-ol
- Item 8.3 Draft BPC opinions on Union authorisation applications for a product family containing iodine / PVP-iodine

Wednesday 11 December: afternoon session

- Item 9.1 Introduction of ECHA Read-across assessment framework in biocides
- Item 9.2 Request to ECHA on guidance for risk assessment for bees
- Item 10 Action points and conclusions

End of meeting 000