27 November 2015

BPC-M-12-2015

Final minutes of the 12th meeting of the Biocidal Products Committee (BPC)

30 September – 1 October 2015

Part I - Summary Record of the Proceedings

1. Welcome and apologies

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

The Chairman mentioned the latest changes in the BPC membership, namely: (i) appointment of new member for Malta, namely Wayne Giordmaina; (ii) appointment of Svenja Ensch as Luxembourgish alternate member. He also mentioned that this was the first meeting in which the Swiss member Manuel Rusconi participated.

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

Five advisers, one invited expert, one representative of the European Commission and one representative from accredited stakeholder organisations (ASOs) were present at the meeting. Apologies were received from two members and two ASO representatives.

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

2. Agreement of the agenda

The Chairman introduced the final draft agenda (BPC-A-12-2015_rev5) and indicated that two agenda items had to be postponed to BPC-13; the items are "Disseminating the revised Assessment Report following the submission of data after active substance approval", for which a document will be prepared for the next BPC meeting, and "Proposal to revise the working procedure", on which the SECR will come back under agenda item 9.

The Chairman invited then any additional items. No additional items were included in the agenda.

The agenda was adopted with the proposed changes. The final version of the agenda will be uploaded to the BPC CIRCABC IG as part of the meeting minutes.

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

The list of meeting documents and the final version of the agenda are included in Part IV of the minutes.

3. Declarations of potential conflicts of interest to the agenda

The Chairman invited BPC members, alternates and advisers to declare any potential conflicts of interest in relation to the agreed agenda. None was declared.

4. Agreement of the draft minutes and review of actions arising from BPC-11

The revised draft minutes from BPC-11 (BPC-M-11-2015), incorporating the comments received from members, were agreed.

Under the follow-up of the actions arising from BPC-11, it was communicated to BPC members that with regard to the scenario for the use of disinfectants in footbaths, on the small scale applications the following was concluded at WG-III-2015: i) A request for the development of specific small scale applications for PT 2, PT 3 and PT 4 would be send to the Ad-hoc Working Group on Environmental Exposure. This request was sent by ECHA after WG-III-2015. ii) An interim solution was proposed for PT 2 and PT 4 (using 10% of the default surface areas in the respective scenarios), for PT 3 however no interim solution was proposed because of doubts of the WG Environment, that 10% of a stable would in reality be treated with an RTU product.

On the launch of an e-consultation on the environmental risk assessment for biphenyl-2-ol for PT 3, the Chairman reported that this was initiated and that the revised opinion is scheduled for BPC-13. The same was reported concerning the launch of an e-consultation on the environmental risk assessment for cyromazine for PT 18.

On the amended PNEC value for imidacloprid and possible implications for product authorisation, the Chairman mentioned that the Commission was consulted and the issue will be discussed in the following Coordination Group meeting. The revised assessment report has been distributed on the website and stakeholders have been informed via the ECHA stakeholder newsletter.

The Chairman informed the BPC about an applicant's request for confidential treatment of the respective opinions since this would undermine their commercial interest and would favour competitors. It was communicated that ECHA rejected this request as: i) it is considered a normal outcome of the regulatory process that opinions on competing active substances are delivered at different times; ii) there is an overriding public interest in disclosing the opinions after the adoption by the Committee.

Actions:

- **SECR:** to upload the agreed minutes from BPC-11 to the BPC CIRCABC IG and to the ECHA website after the meeting;

5. Administrative issues

5.1 Housekeeping issues

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

5.2 Administrative updates and report from other ECHA bodies

The Chairman introduced document BPC-12-2015-01 covering the report from the other ECHA Committees and provided to members for information purposes. One member suggested that it would be useful to insert in the report relevant links to the ECHA

website. It was also pointed out that in the harmonised classification and labelling section it would be beneficial to highlight the substances which are biocides.

The members were informed that the migration to Secure CIRCABC has been postponed until further notice. Members were however reminded to update their ECAS account by adding their mobile phone number.

The Chairman informed that a new organisation, EuroCommerce (representing commerce federations, retail, wholesale and other trading companies in Europe) has been accepted as one of ECHA's accredited stakeholders and expressed an interest to participate in the updating of guidance documents related to biocides. Following the agreement of the BPC to accept this organisation as an accredited stakeholder, the list of accredited stakeholders published on the ECHA website will be updated.

Actions:

- **SECR:** to update the accredited stakeholders list on the ECHA website.

6. Work Programme for BPC for 2015– 2016

6.1 Revised Work Programme 2015-2016

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

With respect to the Working Group meeting in May 2016 and the BPC in October 2016, the Chairman informed that the dossier "Silicic acid, aluminium magnesium sodium salt" previously indicated as an application for Annex I inclusion, has been resubmitted as a regular application under Article 7 of the BPR.

The Chairman informed the meeting that following discussions at the Competent Authorities meeting on the renewal of anticoagulant rodenticides, these are scheduled to be discussed at the BPC meeting in June 2016. Considering the relatively low number of dossiers scheduled for this meeting it seems feasible to schedule the renewal dossiers for that meeting. One member expressed concerns that this planning, if it also includes discussions at the Working Groups, would have implications on the workload of the Working Groups. The Chairman clarified that since it is expected that the eCAs regard the renewal applications as one not requiring a full evaluation (meaning only 90 days are foreseen for the peer review leading to the BPC opinion) a discussion at the Working Groups is currently not foreseen. Members were reminded that more detailed discussions on the topic were foreseen under agenda item 10.1 to be discussed the following day.

As concerns Union Authorisations and the possible discussions on the formation of a parallel committee which would deal with them, the Chairman was of the opinion that under the current circumstances (likelihood for discussions on Union authorisations to start in the first half of 2017 and possibility to absorb these discussions in the future work of this Committee considering the current number of applications) there is no need to start such discussions, at least for the time being.

The Chairman informed the BPC members that the dossiers from the Review Programme will be migrated to R4BP3 after the first BPC meeting in 2016. This would imply that SECR will take over some tasks currently performed by eCAs. It was pointed out that the envisaged use of R4BP3 will also allow better reporting.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) to the SECR by 9 October 2015.
- **SECR**: on the basis of the changes to update the WP on the ECHA web site and in the BPC CIRCABC IG.

6.2 Outlook

This agenda item was discussed under item 6.1.

7. Applications for approval of active substances

7.1 Draft BPC opinion on Bardap 26 for PT 8

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

SECR noted that following the endorsement of the document on "Wording of the conditions of approval of active substances" at the last CA meeting, the opinion will need to be rewritten. Sections 2.3, 2.4, and 2.5 of the opinion will therefore be sent for a written commenting round and sent to the next BPC meeting for adoption.

The rapporteur introduced the substance and pointed out that final conclusions could be drawn on use classes 1 and 2 only although the application included also use class 3 and 4a. The use classes 3 and 4a could not be fully assessed: the assessment was done for ground and surface water only but not for soil and sediment. Additional studies are required if use classes 3 and 4a are sought at product authorisation, in particular ecotoxicological data for soil and sediment organisms.

General issues related to the assessment report (AR) and opinion were discussed in detail. The following issues were agreed (modifications are described in the open issues table):

- With regards to the PBT status, it was discussed whether "not P" or "potential P" should be indicated in the AR and opinion since there is insufficient data to determine its status while there are indications that the substance may be persistent. It was agreed that until further information is provided, based on the information available Bardap 26 can be considered as potential P. The AR will detail which additional studies are required to clarify the P status. These additional studies should be submitted at the latest 6 months before the approval of the active substance.

- For the endpoints where read-across to DDAC was applied the List of Endpoints (LoEP) reflects the updated combined LoEP for DDAC. However, only the LoE has been revised accordingly. This will be indicated in the relevant parts of the AR.
- When PPE is requested only to protect from local dermal effects, as the local risk assessment is semi-quantitative the protection factors do not need to be specified. The type of PPE required is subject to the local risk assessment of the specific use.
- Regarding the provision related to food and feeding stuff and residue data, though the provision was not applied for other PT 8 substances, it was agreed to remain to be consistent with other QUATs in PT 8.
- Requirement for a test on Daphnia in section 2.5 will remain since the test will be submitted by the applicant to confirm the validity of the read-across with DDAC.

Regarding the revision of sections 2.3, 2.4 and 2.5, some initial proposals were discussed. The following issues would need be finally agreed during the written commenting round: i) whether the condition number 4 should be kept in 2.3 or whether the risk mitigation measures should be described in 2.4; and ii) need to note in section 2.4 that use classes 3 and 4 has not been fully evaluated.

The Assessment Report was agreed by the BPC, subject to the changes agreed during the meeting. The opinion will be sent for a written commenting round and sent to the BPC meeting in December for adoption.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 21 January 2016
- **Rapporteur:** to revise the opinion in consultation with the SECR, reflecting the discussions in the BPC and applying the new wording in sections 2.3, 2.4 and 2.5 by 22 October 2015.
- **SECR:** to launch a consultation on the revised sections 2.3, 2.4 and 2.5 of the opinion. The written procedure will contain the revised draft opinion in accordance with the discussions in the BPC and applying the new wording of the conditions.

7.2 Draft BPC opinion on DBDCB for PT 6

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

SECR noted that following the endorsement of the document on "Wording of the conditions of approval of active substances" at the last CA meeting, the opinion will need to be rewritten. Sections 2.3, 2.4, and 2.5 of the opinion will therefore be sent for a written commenting round and sent to the next BPC meeting for adoption.

The rapporteur introduced the substance and pointed out that the only use that was evaluated in the dossier was decorative paintings for indoor use. The rapporteur also mentioned that the substance was discussed at TM-IV-2010 and the outcome of the

Human Health-TM was "closed with no outstanding issues". The environment part was re-discussed at WG-III-2015.

Several members pointed out that a general discussion is required for how to handle active substances that were discussed at TM and for which only some part(s) are discussed again at a WG meeting. SECR noted that this would be a point for discussion under item 8 of the Agenda.

General issues related to the assessment report (AR) and opinions were discussed in detail. The following issues were agreed (modifications are described in the open issues table):

- A CLH proposal needs to be submitted to RAC within one month after the adoption of the BPC opinion. One Member pointed out that their concern is about the potential allergic reactions of people using paint containing the active substance and not about the correctness of the CLH proposal.
- A provisional dermal absorption value was agreed and MSs should use the EFSA guidance at product authorisation stage.
- The long-term AEL as agreed at TM IV-2010 should be kept. The rapporteur shall use the new ECHA guidance to derive the AEL and present the document to the Human Heath WG, after the opinion has been adopted, so that the LoEP can be changed.
- The substance should be considered as "potentially P". The DT50 as proposed by the rapporteur (DT50 in soil of 1000 days instead of 1 day, following ENV WG-III-15 discussion) should be used for the risk assessment in soil and the CAR should be revised accordingly. Additional data on soil and sediment degradation are required in order to clarify the P-criterion.
- A risk assessment for ground water needs to be added.

The Assessment Report was agreed by the BPC, subject to the changes agreed during the meeting. The opinion will be sent for a written commenting round and sent to the BPC meeting in December for adoption.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 21 January 2016
- **Rapporteur:** to revise the opinion in consultation with the SECR, reflecting the discussions in the BPC and applying the new wording in sections 2.3, 2.4 and 2.5 by 22 October 2015.
- **SECR:** to launch a consultation on the revised sections 2.3, 2.4 and 2.5 of the opinion. The written procedure will contain the revised draft opinion in accordance with the discussions in the BPC and applying the new wording of the conditions.

7.3 Draft BPC opinion on Ampholyt 20 for PT 2 and 4

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

SECR noted that following the endorsement of the document on "Wording of the conditions of approval of active substances" at the last CA meeting, the opinion will need to be rewritten. Sections 2.3, 2.4, and 2.5 of the opinion will therefore be sent for a written commenting round and sent to the next BPC meeting for adoption.

General issues related to the assessment report (AR) and opinions were discussed in detail. The following issues were agreed (modifications are described in the open issues table):

- In the AR it will be indicated that a conservative approach has been followed for the assessment of the environmental risks (i.e. a high and low Koc value has been used).
- It was agreed that the proposed risk mitigation measures (RMM) are needed to reduce the risks to an acceptable level, but further information may be required at product authorisation on the effectiveness of these RMM. Another option could be to submit additional at product authorisation to show that there is no risk (for the sediment compartment) and that the RMM are not further needed.
- An overall conclusion on the identified safe uses will be included in the opinion.
- eCA and the applicant will discuss bilaterally the possibility of revising the tonnage approach calculations. The tonnage used refers to the total PT 2 volume and no distinction between the different ways of application has been made. Thus the tonnage value could be broken down to account for the RTU consumption.

The Assessment Report was agreed by the BPC, subject to the changes agreed during the meeting. The opinion will be sent for a written commenting round and sent to the BPC meeting in December for adoption.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 21 January 2016
- **Rapporteur:** to revise the opinion in consultation with the SECR, reflecting the discussions in the BPC and applying the new wording in sections 2.3, 2.4 and 2.5 by 22 October 2015.
- **SECR:** to launch a consultation on the revised sections 2.3, 2.4 and 2.5 of the opinion. The written procedure will contain the revised draft opinion in accordance with the discussions in the BPC and applying the new wording of the conditions.

7.4 Outcome of the written procedure for peracetic acid PT 1-6

The Chairman informed the participants on the outcome of the written procedure launched on 14 July 2015 on the proposed reference specification by the rapporteur. The written procedure, launched in accordance with Article 20 of the Rules of Procedure of the BPC, contained the new proposal of the rapporteur for the reference specification and the revised opinions. The Chairman reported that seventeen members having the right to vote reacted to the written procedure, which therefore was valid. Sixteen members agreed on the proposal on the reference specification subject to some minor comments. One member disagreed with the proposal but agreed after receiving the response to their comments from the rapporteur. Seventeen members voted in favour of the revised opinions subject to some minor comments, meaning that the opinions for peracetic acid for PT 1 - 6 were adopted.

Actions:

- **SECR:** to forward the final opinions to COM **by 23 October 2015** and publish them on the ECHA website.
- **Rapporteur**: to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR by **12 November 2015**

8. Draft BPC opinion pursuant to Article 75(1)(g) on sulfuryl fluoride for PT 8 and 18

The Chairman invited the rapporteur to introduce the opinion, mentioning that the opinion has undergone a commenting round.

The rapporteur introduced the substance explaining that at the time when sulfuryl fluoride was included in Annex I to Directive 98/8 for both PT 8 and PT 18 there were already concerns for the greenhouse gas potential of this substance but very limited information was available in order to assess its global warming potential. Both Inclusion Decisions were associated with a specific condition for monitoring concentrations of sulfuryl fluoride in remote tropospheric air. In compliance with this specific condition, the authorisation holder submitted monitoring data from remote tropospheric air to the Commission in January 2014. The rapporteur concluded that the data submitted by the authorisation holder were in line with the requirements and that, together with the two studies, they indicated that the previous estimated global warming potential was an underestimation. However, the amount released to the atmosphere is substantially lower than that of other greenhouse gases: the calculations performed show an estimated contribution of sulfuryl fluoride to global warming of 0.03%. Considering that in the next two years a dossier for renewal will have to be submitted, the rapporteur suggested that the assessment could be updated in that context to incorporate the new conclusions.

During the commenting round and also during the discussions in the meeting two members suggested the inclusion in the conclusive part of the opinion a phrase concerning risk mitigation measures to be applied to prevent the release of this substance into the atmosphere. Both SECR and COM were of the view that the provision of risk mitigation measures at this stage might be premature since no full assessment has yet been performed. A short discussion followed on the most appropriate wording to be used concerning the risk mitigation measures and the following wording was agreed

for the last conclusion: "At renewal stage the possibility of risk mitigation measures in order to reduce the emissions to air needs to be addressed".

Actions:

- **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 23 October 2015** and publish it on the ECHA website.

9. Working procedure for the active substance approval process

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

The Chairman introduced the document) and noted the changes made. The Chairman also indicated that the document needs to be amended following the document on "Wording of the conditions of approval of active substances", which was endorsed at the last CA meeting.

Actions:

- **SECR:** to amend the document in light of the adopted CA document on the wording of the conditions for active substance approval and present it at BPC-13.

9.1 b) Revised templates for BPC opinions and assessment reports

This agenda item was not discussed. It was decided to initiate first a commenting round.

Actions:

- **SECR:** to open a Newsgroup on CIRCABC for commenting the revised templates.
- **Members:** to send comments by **2 November 2015**.

9.2 Follow-up on the Workshop "Reviewing the active substance assessment process"

a) A proposal to revise the working procedure

This agenda item was moved to the next BPC meeting.

b) Applicability of new guidance and guidance related documents

SECR presented the document. BPC members asked for clarification on how to deal specifically with dossiers put on hold (e.g. if RAC decision is awaited) and with back log dossiers, for which reference was made to Art. 90(2) of the BPR.

For guidance documents as such, the proposed timeline of one year was questioned. It should be aligned with the timeline for guidance related to product authorisation, for which a timeline of two years applies. Specific proposals included the application of new guidance directly immediately after publication if no guidance at all is currently available, and the application of updated guidance two years after publication.

It was further noted that parameterisation and the proposed timeline of three month for some guidance related documents should be revised and further specified, taking e.g. into account also different stakeholders (CAs and applicants).

The postponement of the application at renewal stage in case of unequal treatment was questioned; if corrections of current guidance are needed because there are mistakes, it should apply immediately, taking into account also potential unequal treatment. COM clarified regarding Art. 90(2) that this article relates to information requirements, not to guidance.

Actions:

- **SECR:** to open a Newsgroup on CIRCABC for commenting the document and to prepare a revised version for BPC-13 in light of the discussions at BPC-12 and of the comments received. The SECR will consider in particular:
  - Timelines for application of new guidance;
  - Special situations (e.g. backlog, dossier put on hold);
  - Clarity on when to apply flexibility and exceptions.

- **Members:** to send comments by **2 November 2015**.

c) The role of the BPC Secretariat in the active substance approval process

The Chairman introduced the document. Members welcomed the document and found it helpful to better define the roles of the different parties in the active substance approval process.

Members requested some further information about SECR's proposal to prepare a more elaborated checklist for the accordance check. SECR explained that the checklist should focus on issues that are essential for the peer review process and might contain issues that are not included at present. A draft will be prepared by SECR and discussed in the Working Groups.

The proposal to go through the 'backlog' dossiers was supported and it was suggested that the updated list for accordance checks could be useful in this work, as well as in the evaluation performed by the eCA.

COM proposed to introduce a paragraph that elaborates further the procedures and responsibilities around the public consultation of CARs for active substances that potentially meet the exclusion criteria. It was also proposed by members to include paragraphs on roles and responsibilities during the Working Group and BPC meetings, as well as after the adoption of the opinion in the BPC.

Other points where members or the ASO representative requested clarification concerned information and contact details of the ECHA dossier manager, contacts between ECHA and the applicants, and coordination between the Working Groups and the BPC.

Actions:

- **SECR:** to open a Newsgroup on CIRCABC for commenting the document.
- **SECR:** to present a revised version for information at BPC-13 in light of the discussions at BPC-12 and of the comments received.
- **Members:** to send comments by 2 November 2015.

d) Possibility of introducing new data or new information during the peer review process

The Chairman introduced the document. Several members and an ASO representative stated that it should be more clearly indicated in the document that normally a dossier must be complete and no additional data are needed, once the Draft CAR is finalised and submitted for peer review by the eCA. Several members requested a procedure including a peer review by the relevant Working Group on the evaluation of the new data by the eCA. Members sought clarification on: i) whether hazard data can be submitted instead of data on exposure and use data; ii) the possibility to submit new information in cases where 'obvious mistakes' in the evaluation of the eCA have a significant negative impact for the applicant; iii) the possibility to submit new information also by MSCAs; iv) the possibility to submit new information in cases where this information would indicate that there are unacceptable risks; v) if all conditions listed in the document have to be fulfilled before new information is allowed; vi) if new information can be allowed in case a dossier is put on hold for a significant period of time (awaiting the opinion of the RAC for example). SECR stated these comments will be considered and also invited members to comment on these issues. A member indicated that the eCA should be alert in the commenting phase of the Draft CAR on comments which may indicate that new information may be requested by Working Group members. The eCA can in such cases already start consultations with the applicant.

Actions:

- **SECR:** to open a Newsgroup on CIRCABC for commenting the document.
- **SECR**: to prepare a revised version for BPC-13 in light of the discussions at BPC-12 and of the comments received.
- **Members:** to send comments by **2 November 2015**.

10. Any other business

10.1 Renewal of anticoagulant rodenticides active substances: coordinating role of ECHA

The SECR informed BPC members on the upcoming renewal of anticoagulant rodenticides (AVK) active substances, which was discussed at the latest CA meeting (16-18 September) and on the possible coordinating role that ECHA will play.

The discussion was initiated with the members on the way forward with respect to the renewal process and especially on the expectations of the involved members with respect to the coordinating role of ECHA. Some eCAs for AVKs informed that they have

received new data or information from the applicant. Most of the eCAs stated that a full evaluation would not be needed. The members expected that the focus of the renewal would be on resistance, efficacy and RMM. The members expressed their need to have guidance and coordination on the expected outcome i.e. what needs to be done and by when if no full evaluation is needed. It was proposed that ECHA would host a meeting or teleconference for the eCAs to come to a harmonised approach for the evaluation.

COM clarified that only those parts where new data is submitted needs to be re-evaluated and the evaluation should include an eCA assessment whether the previous conclusion of the assessment is still valid. COM also highlighted that the main focus of the renewal of AVKs, in addition to the resistance and new data submitted, would be re-evaluation of the appropriate RMMs. IND supported focusing the re-evaluation on a harmonised approach for RMM.

The SECR noted that it would be reasonable to avoid postponing issues to product authorisation since it creates a risk for non-harmonised approaches and duplicate work. SECR also noted that expectations should be agreed before the template could be provided.

The Chairman informed the BPC that for the next meeting a dedicated opinion template will be developed by the SECR.

Actions:

- **SECR:** to initiate a consultation between the involved eCAs, COM and SECR to agree on the expected outcome and underlying principles by setting up a teleconference, after discussing with COM on resources and priorities.
- **SECR**: to prepare an opinion template for renewal of AVKs for BPC-13.
- **Involved eCAs:** to inform SECR on the status of their dossiers.

11. Agreement of the action points and conclusions

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

Part II - Main conclusions and action points

Agreed at the 12th meeting of BPC

30 September – 1 October 2015

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 further 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-11	
The revised version of the minutes of BPC-11 was agreed as proposed subject to several editorial modifications and the removal of parts from the section related to PHMB due to confidentiality reasons.	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website after the meeting.
Item 6 - Work programme for BPC	
6.1 Revised Work Programme 2015-2016	
Priority shall be given to the first and second priority list substances of the Review Programme Regulation.	**Members:** to send information on any further changes to the Work Programme (WP) to the SECR **by 9 October 2015**. **SECR:** on the basis of the changes to update the WP on the ECHA web site and in the BPC CIRCABC IG.
6.2 Outlook	
	Members: to comment on the outlook **by 31 October 2015**. **SECR:** to prepare an overview of the dossiers on the first priority list which will be submitted after the legal deadline and submit it to COM.
Item 7 - Applications for approval of active substances	
7.1 Draft BPC opinion on Bardap 26 for PT 8	
The BPC agreed on the opinion for the approval of this active substance/PT combination. However, the sections 2.3 , 2.4 and 2.5 will be amended incorporating the CA document on the "Wording of the conditions of approval of active substances". A written commenting round will be launched after the BPC followed	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **21 January 2016** **Rapporteur:** to revise the opinion in consultation with the SECR, reflecting the discussions in the BPC and applying the new wording in sections 2.3, 2.4 and 2.5 by **22 October 2015**.

by the intention to adopt the opinion at BPC-13.	**SECR:** to launch a consultation on the revised sections 2.3, 2.4 and 2.5 of the opinion. The written procedure will contain the revised draft opinion in accordance with the discussions in the BPC and applying the new wording of the conditions.
7.2 Draft BPC opinion on DBDCB for PT 6	
The BPC agreed on the opinion for the approval of this active substance/PT combination. However, the sections 2.3 , 2.4 and 2.5 will be amended incorporating the CA document on the "Wording of the conditions of approval of active substances". A written commenting round will be launched after the BPC followed by the intention to adopt the opinion at BPC-13.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by **21 January 2016** **Rapporteur:** to revise the opinion in consultation with the SECR, reflecting the discussions in the BPC and applying the new wording in sections 2.3, 2.4 and 2.5 by **22 October 2015**. **SECR:** to launch a consultation on the revised sections 2.3, 2.4 and 2.5 of the opinion. The written procedure will contain the revised draft opinion in accordance with the discussions in the BPC and applying the new wording of the conditions.
7.3 Draft BPC opinion on Ampholyt for PT 2 and PT 4	
The BPC agreed on the opinions for the approval of these active substance/PT combinations. However, the sections 2.3 , 2.4 and 2.5 will be amended incorporating the CA document on the "Wording of the conditions of approval of active substances". A written commenting round will be launched after the BPC followed by the intention to adopt the opinion at BPC-13.	**Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR by **21 January 2016** **Rapporteur:** to revise the opinions in consultation with the SECR, reflecting the discussions in the BPC and applying the new wording in sections 2.3, 2.4 and 2.5 by **22 October 2015**. **SECR:** to launch a consultation on the revised sections 2.3, 2.4 and 2.5 of the opinion. The written procedure will contain the revised draft opinion in accordance with the discussions in the BPC and applying the new wording of the conditions.
7.4 Outcome of the written procedure for peracetic acid for PT 1-6	
The SECR informed the BPC on the outcome of the written procedure. The BPC adopted the opinions by consensus via the written procedure.	**SECR:** to forward the final opinions to COM **by 23 October 2015** and publish them on the ECHA website. **Rapporteur**: to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR by **12 November 2015**
Item 8 – Opinions pursuant to Article 75 (1)(g)	
8. Draft BPC opinion pursuant to Article 75(1)(g) on sulfuryl fluoride for PT 8 and 18	
The BPC adopted by consensus the opinion pursuant to Art 75(1)(g).	**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 23 October 2015** and publish it on the ECHA website.
Item 9 - Working procedure for the active substance approval process	
9.1 a) Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval	
	SECR: to amend the document in light of the adopted CA document on the wording of the conditions for active substance approval and present it at BPC-13.
9.1 b) Revised templates for BPC opinions and assessment reports	
	SECR: to open a Newsgroup on CIRCABC for commenting the revised templates. **Members:** to send comments by **2 November 2015**.
9.2 Follow-up on the Workshop "Reviewing the active substance assessment process"	
9.2 b) Applicability of new guidance and guidance related documents	
	SECR: to open a Newsgroup on CIRCABC for commenting the document. **SECR:** To prepare a revised version for BPC-13 in light of the discussions at BPC-12 and of the comments received. The SECR will consider in particular: - Timelines for application of new guidance; - Special situations (e.g. backlog, dossier put on hold); - Clarity on when to apply flexibility and exceptions. **Members:** to send comments by **2 November 2015**.
9.2 c) The role of the BPC Secretariat in the active substance approval process	
	SECR: to open a Newsgroup on CIRCABC for commenting the document. **SECR:** to present a revised version for information at BPC-13 in light of the discussions at BPC-12 and of the comments received. **Members:** to send comments by **2 November 2015**.
9.2 d) Possibility of introducing new data or new information during the peer review process	
	SECR: to open a Newsgroup on CIRCABC for commenting the document. **SECR**: to prepare a revised version for BPC-13 in light of the discussions at BPC-12 and of the

	comments received. **Members:** to send comments by **2 November 2015**.
Item 10 – Any other business	
10.1 Renewal of anticoagulant rodenticides active substances: coordinating role of ECHA	
	Involved eCAs: to inform SECR on the status of their dossiers. **SECR:** to initiate a consultation between the involved eCAs, COM and SECR to agree on the expected outcome and underlying principles.

Part III - List of Attendees

Members	European Commission
BORGES Teresa (PT)	CHATELIN Ludovic (DG SANTE)
BROVKINA Julija (LV)	
ČEBAŠEK Petra (SI)	**Advisers**
COSTIGAN Michael (UK)	MIKOLAS Jan
DONS Christian (NO)	PALOMÄKI Jaana
DRAGOIU Mihaela-Simona (RO)	PLATTNER Edmund
GONZALEZ MARQUEZ Luisa (ES)	VOMASTKOVA Milada
HADJIGEORGIOU Andreas (CY)	WEINHEIMER Viola
HAHLBECK Edda (SE)	
HARRISON John (IE)	**Accredited Stakeholder Organisations**
JÄGER Stefanie (DE)	BRUYNDONCKX Raf (Cefic)
KOMEN Corine (NL)	
LARSEN Jørgen (DK)	**ECHA Staff**
MERISTE Anu (EE)	JANOSSY Judit
MIKOLASKOVA Denisa (SK)	KENIGSWALD Hugues
RUSCONI Manuel (CH)	MYOHANEN Kirsi
SPATNY Nina (AT)	NEGULICI Ligia
SZÁNTÓ Emese (HU)	SCHIMMELPFENNIG Heike
TUUSA Tiina (FI)	THUVANDER Ann
VACEK Tomáš (CZ)	VAN DE PLASSCHE Erik
VAN BERLO Boris (BE)	
VRHOVAC FILIPOVIC Ivana (HR)	
ZIGRAND Jeff (LU)	
ZOUNOS Athanasios (EL)	
Alternate members	
COLLET Romy (FR)	
CRESTI Raffaella (IT)	
Invited expert	
HUSZAL Sylwester (PL)	

Applicants	Apologies
FREEMANTLE Mike (Lonza) for Bardap 26 PT 8	CAZELLE Elodie (AISE)
GROTH Torsten (Lanxess) for DBDCB PT 6	GIORDMAINA Wayne (MT)
LEONHARDT Wolfgang (Evonik Nutrition & Care GmbH) for Ampholyt PT 2 and 4	MAJUS Saulius (LT)
WORTHINGTON Mark (Eurofins Regulatory AG) for sulfuryl fluoride PT 8 and 18	REID Kirsty (Eurogroup for Animals)
Experts accompanying applicants	
SCHOLTZ Rudolf, accompanying FREEMANTLE Mike, for Bardap 26 PT 8	
WERNER Michael, accompanying GROTH Torsten, for DBDCB PT 6	
HALL Caroline, accompanying LEONHARDT Wolfgang, for Ampholyt PT 2 and 4	

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-12

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-12 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2	BPC-A-12-2015	Draft agenda	
4	BPC-M-11-2015_draft	Draft minutes from BPC-11	
5.2	BPC-12-2015-01	Administrative issues and report from the other ECHA Committees	
6.1	BPC-12-2015-02	BPC updated Work Programme 2015-2016	
6.2	BPC-12-2015-03	Outlook	
7.4	BPC-12-2015-17	Outcome of the written procedure for peracetic acid PT 1-6	
9.1a)	BPC-12-2015-04	Catalogue of specific conditions and elements at the product authorisation stage	
9.1b)	BPC-12-2015-15 BPC-12-2015-16	Revised templates for BPC opinions and assessment reports	
9.2 b)	BPC-12-2015-07	Applicability of new guidance and guidance related documents	
9.2 c)	BPC-12-2015-08	The role of the BPC Secretariat	
9.2 d)	BPC-12-2015-09	Possibility of introducing new data or new information during the peer review process	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.1	BPC-12-2015-10A	Bardap 26 PT 8	Draft opinion
	BPC-12-2015-10B		Assessment report
	BPC-12-2015-10C		Open issues
7.2	BPC-12-2015-11A	DBDCB PT 6	Draft opinion
	BPC-12-2015-11B		Assessment report
	BPC-12-2015-11C		Open issues
7.3	BPC-12-2015-12A	Ampholyt PT 2	Draft opinion
	BPC-12-2015-12B		Assessment report

	BPC-12-2015-12C		Open issues
7.3	BPC-12-2015-13A	Ampholyt PT 4	Draft opinion
	BPC-12-2015-13B		Assessment report
	BPC-12-2015-13C		Open issues
8	BPC-12-2015-14	Sulfuryl fluoride	Draft opinion

25 September 2015
BPC-A-12-2015_rev5

Final agenda

12th meeting of the Biocidal Products Committee (BPC)

30 September – 1 October 2015

ECHA Conference Centre, Annankatu 18, Helsinki

30 September: starts at 09:00

1 October: ends at 13:00

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-12-2015_rev5

For agreement

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

4. – Agreement of the minutes and review of actions from BPC-11

BPC-M-11-2015

For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

BPC-12-2015-01

For information

6. – Work programme for BPC

6.1. Revised BPC Work Programme 2015-2016

BPC-12-2015-02

For information

6.2. Outlook

BPC-12-2015-03

For information

7. – Applications for approval of active substances*

7.1. Draft BPC opinion on Bardap 26 for PT 8

Previous discussion(s): TM III- 2009 and BPC-9

BPC-12-2015-10A, B and C

For adoption

7.2. Draft BPC opinion on DBDCB for PT 6

Previous discussion(s): 2010 TM IV and WG-III-2015

BPC-12-2015-11A, B and C

For adoption

7.3. Draft BPC opinion on Ampholyt for PT 2 and 4

Previous discussion(s): WG III-2014 and BPC-8

PT 2: BPC-12-2015-12A, B and C

PT 4: BPC-12-2015-13A, B and -12C

For adoption

7.4. Outcome of the written procedure for peracetic acid PT 1-6

BPC-12-2015-17

For information

8. – Opinions pursuant to Article 75(1)(g)

Draft BPC opinion pursuant to Article 75(1)(g) on sulfuryl fluoride

BPC-12-2015-14

For adoption

9. – Working procedure for the active substance approval process

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

BPC-12-2015-04

For information

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

b) Revised templates for BPC opinions and assessment reports

BPC-12-2015-15, BPC-12-2015-16

For information

9.2. Follow-up on the Workshop "Reviewing the active substance assessment process":

a) A proposal to revise the working procedure

For information

b) Applicability of new guidance and guidance related documents

BPC-12-2015-07

For discussion

c) The role of the BPC Secretariat in the active substance approval process

BPC-12-2015-08

For discussion

d) Possibility of introducing new data or new information during the peer review process

BPC-12-2015-09

For discussion

10. - Any other business

10.1. Renewal of anticoagulant rodenticides active substances: coordinating role of ECHA

For discussion

11. – Agreement of the action points and conclusions

For agreement

Provisional timeline for the

12th meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Annankatu 18, Helsinki

30 September 2015: starts at 09:00
1 October 2015: ends at 13:00

Please note that the timings indicated below are provisional and subject to possible change. They are distributed to participants on a preliminary basis. Morning sessions usually start at 09:00.

Wednesday 30 September: morning session

Items 1-5	Opening items and administrative issues
Item 6	Work programme of the BPC 2015-16
Item 7	Applications for approval of active substances
Item 7.1	Draft BPC opinion on Bardap for PT 8
Item 7.2	Draft BPC opinion on DBDCB for PT 6

Wednesday 30 September: afternoon session

Item 7.3	Draft BPC opinion on Ampholyt for PT 2 and 4
Item 7.4	Outcome of the written procedure fro peracetic acid for PT 1-6
Item 8	Draft BPC opinion pursuant to Article 75(1)(g) on sulfuryl fluoride
Item 9	Working procedure for the active substance approval process
Item 9.1	a) Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval b) Revised templates for BPC opinions and assessment reports

Thursday 1 October: morning session

Item 7 (cont'd)	Follow up to previous discussons on draft substance opinions
Item 9.2	Follow-up on the Workshop "Reviewing the active substance assessment process": a) A proposal to revise the working procedure b) Applicability of new guidance and guidance related documents c) The role of the BPC Secretariat in the active substance approval process d) Possibility of introducing new data or new information during the peer review process
Item 10	Any other business
Item 10.1	Renewal of anticoagulant rodenticides active substances: coordinating role of ECHA
Item 11	Agreement of the action points and conclusions

End of meeting

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