BPC-M-2-2013 FINAL
Agreed at BPC-3
(10 October 2013)

Minutes of the 2nd meeting of the Biocidal Products Committee (BPC)

29-30 May 2013

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chair of the Biocidal Products Committee (BPC), welcomed the participants to the second meeting.

The Chair informed BPC members of the participation of 20 members and one alternate. Apologies were received from five members. Three advisers, two representatives of the European Commission, one observer from Croatia and five accredited stakeholder organisations (ASOs) present at the meeting were also introduced. The Chair also introduced the ECHA Secretariat.

Participants were informed that the meeting would be recorded solely for the purposes of writing the minutes and that this recording would be destroyed after the agreement of the minutes. The list of attendees is given in Part III of the minutes.

2. Agreement of the agenda

The Chair introduced the revised draft agenda (BPC-A-2-2013 rev 1) and invited any items under AOB. The agenda was agreed without changes. The list of meeting documents and the final agenda are included in Part IV. Two additional meeting documents were tabled as room documents: BPC-2-2013-11 - Overview of the CLH and PBT status of active substances in the Review Programme; and BPC-2-2013-12 - Participation of observers in the BPC – Industry comments.

3. Tour de table of accredited stakeholder organisations

The Chair invited the representatives of the ASOs to introduce themselves, the organisation they represent and their background.

4. Agreement of the draft minutes from BPC-1

The draft minutes from BPC-1 (BPC-M-1-2013) were agreed without any further changes. The agreed minutes were to be uploaded to the BPC CIRCABC IG and to the ECHA website after the meeting.

5. Administrative issues

5.1. Housekeeping issues

The Secretariat (SECR) informed participants of the housekeeping issues including the safety and security arrangements.

5.2. ICT and submission of evaluations

The SECR presented document BPC-2-2013-01 on the proposed approach for ICT and submission of evaluations.

The Chair explained the rationale for the proposal for the submission of the evaluations and invited the members input on the proposed approach to CIRCABC IG migration and on the relevant documents being available in the future. It was agreed that there will be an on-going need to access the information currently available in the CIRCABC IG 'Biocides-TM'. Therefore this information can be available as an archive.

Actions:

Members were invited to provide any further comments in the dedicated CIRCA Newsgroup by Friday 12 July. The discussion and any further comments will be taken into account when deciding the detailed structure of the CIRCABC IGs.

6. Work programme of the BPC

The SECR presented document *BPC-2-2013-02a* and *BPC-2-2013-02b*. The issues below were raised by participants:

- One member stated that they might not support the document from the CA meeting referred to on page 2 of document CA-May13-Doc.3.0[1];

- Several members expressed concern over not being able to submit draft evaluations to the Agency before the harmonised classification and labelling (CLH) and Persistent, Bioaccumulative and Toxic Expert Group (PBT EG) processes are finalised as proposed in the Commission document for the CA meeting in May (CA-May13-Doc.8.3)[1]. One member stated the principal concern is related to the fact that the evaluation is outsourced;

- It was agreed that the 'backlog' dossiers will be considered in accordance with the Commission's proposed work programme (CA-May13-Doc.8.3) based on priority lists per group of product types. For the detailed work programme a balance will be sought between removing the backlog and dealing with evaluations without unnecessary delay after submission to ECHA. For the detailed work programme the SECR will also consider other mechanisms to increase the overall efficiency, e.g. several active substance evaluations for one product type or considering one active substance for several product types of which some may be ahead of the priority list dead line. The SECR indicated this may be possible in 2014 and 2015 but expressed doubts for later years in relation to the priority lists for disinfectants.

Actions:

Members are invited to provide any further comments in the dedicated CIRCA Newsgroup by Friday 12 July. The SECR will prepare a detailed work programme for BPC-3, taking into account the BPC discussion, the result of the discussion at the July Biocides CA meeting and any further comments from BPC members.

7. Establishing BPC Working Groups

The SECR presented document BPC-2-2013-03 on the establishment of the BPC Working Groups (WGs). The issues below were discussed.

- The overall approach to establishing WGs as described in BPC-2-2013-03 was agreed;

- Revision of the mandates: it was proposed that 'residue definition' in the mandate of WG II (Analytical Methods and Physico-chemical Properties) would be amended to specify 'residues: analytical methods and validation' and the 'residue definition' will be moved to the mandates of WG III (Human Health) and WG IV (Environment). It was also suggested that the term 'proposed risk management measures ' would replace 'proposed risk mitigation measures' in WG III and IV. The mandate of WG III should also cover animal health; animal health in this case referred to companion animals. The Secretariat would further reflect on how to include this in the mandates of the WGs;

- Additional Ad Hoc WGs: one member identified the need for an Ad Hoc WG for comparative assessment;

- BPC Ad Hoc WGs: it was agreed to continue the work of the current HEEG[2] and DRAWG[3] groups through the mechanism of BPC Ad Hoc WGs.

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[1] https://circabc.europa.eu/w/browse/92668ddd-fd3e-4b7e-9232-b80686747060

[2] Human Exposure Expert Group

[3] Dietary Risk Assessment Working Group

Actions:

The SECR was to revise the mandates according to the discussion and on this basis send out invitations to MSCAs to nominate core members and propose flexible members. In addition, the SECR was to reflect further on the need for an ad hoc WG on comparative assessment and to prepare a mandate(s) for the work of BPC Ad Hoc WG(s) for the next meeting, covering the issues currently considered by HEEG and DRAWG.

8. Participation of applicants and stakeholders in the BPC

The SECR presented document BPC-2-2013-04 rev 1 highlighting the changes made after BPC-1. The ASOs: CEFIC, AISE and CEPC presented room document BPC-2-2013-12, Participation of observers in the BPC - IND comments. This agenda item included a closed session. The following issues were raised:

- The majority of the members intervening recommended the participation of applicants in the BPC and accredited stakeholder organisations (ASOs) in the BPC for Type II processes (in addition to the other processes as described the document BPC-2-2013-04 rev 1). These members argued that the participation of applicants leads to an increase in efficiency as they are able to provide clarification for members which then helps the opinion-forming process. Several members argued for the participation of applicants for transparency reasons;

- It was agreed that critical information should be provided well in advance of the BPC meeting in accordance with the Code of Conduct for Stakeholders. To further clarify this, a specific code of conduct for the participation of applicants should be considered. Alternative mechanisms for the involvement of applicants in the BPC should be considered e.g. virtual participation. The SECR stated that with respect to virtual participation confidential business information (CBI) aspects have to be considered as well as the administrative burden. Consequently, the SECR will consider limiting the number of applicants in such virtual participation;

- The importance was agreed of consultation between the evaluating Competent Authority (eCA) and the applicant after the Working Group phase and, where relevant, ad-hoc follow-up process.

Actions:

The SECR will incorporate the conclusions into a proposal for the ECHA Management Board in June. After receiving the advice from the Board, the ECHA Executive Director will decide on the approach to be followed.

The SECR will include in the relevant working procedures consultation between the applicant and the eCA after the Working Group stage including the ad-hoc follow-up.

9. Rules of procedure

To take into account the issues raised at BPC-1, the SECR presented a revised version of the draft Rules of Procedure (RoPs) in document BPC-2-2013-05.

A discussion took place in which the following concerns were raised:

- Some members would like the flexibility to have another individual from the CA instead of the BPC rapporteur to participate in BPC Working Groups;

- The five day period for urgent written procedures (Article 20(2)) is insufficient for some members to react;

- One member indicated that if a rapporteur is replaced on the grounds of an interest coming to light that might be prejudicial to the independent consideration of the case (Article 9(5)); it would like the alternate member to replace the rapporteur.

A discussion took place in the margins to further consider the above issues and this resulted in a new version of the RoPs BPC-2-2013-05 revision 2 (dated 30 May 2013). The new version contained several modifications and was agreed:

- Delete the urgent written procedure process (Article 20);
- Provide sufficient flexibility to allow other persons proposed by the MSCAs to attend BPC WGs instead of the rapporteur (Article 18).

Concerning Article 9(5), the SECR explained that according to the Article 75(4) of the BPR, which in turn refers to Article 87 of REACH, it is not possible to replace a rapporteur BPC member with an alternate. Therefore another BPC member would need to be chosen to replace the rapporteur if the circumstances in Article 9(5) arise. The wording therefore was unchanged. The AT member expressed reservations in relation to Articles 9(5) and 17(2).

Actions:

The SECR to forward the agreed RoPs to the ECHA Management Board for approval and to upload the new version of the RoPs BPC-2-2013-05 revision 2 (dated 30 May 2013) to CIRCA BC.

10. Working procedures and templates

10.1 Approval of active substances

The SECR introduced paper BPC-2-2013-06 & BPC-2-2013-07 & BPC-2-2013-08 BPC-2-2013-09. The issues below were discussed.

- Several members asked for clarifications to be included on the handling of applications provided before 1 September 2013. The SECR will include further text to clarify the approach for these applications in the Working Procedure;
- Several members proposed to remove the rapporteur's name from BPC opinions since members are representing their MSCA. The SECR agreed with this proposal;
- Two members proposed to include the listing of endpoints in the BPC opinion. The SECR will consider whether this would be useful and possibly include the proposal in the next version of the document;
- Several members expressed their concern on the possible need of changing an existing evaluation into the new Competent Authority Report (CAR) format. The SECR confirmed that the substances currently under evaluation in the MSCAs would not need to be changed according to the new CAR structure. A cut-off date would be agreed later, after which all CARs should be provided in the new format. The SECR will also clarify that the Doc III level for active substances in the Review Programme does not need to be provided as a IUCLID file and that the submission of either the IUCLID file or the Doc III is part of the submission of the evaluation by the eCA to the Agency;
- The possibility was discussed of incorporating a public consultation of all the Assessment Reports submitted by eCAs for the Review Programme, in line with Article 16 of Regulation 1451/2007. This will be clarified by SECR and COM, and the possible change in the approach will be included in the revised Working Procedure;
- As a response to a question from one member, the SECR confirmed that when public consultations are launched, MSCAs will receive a notification;
- One member requested clarification that new issues coming up in the discussions should be avoided and therefore issues should be discussed only if the comments

have been sent in time and they are in the discussion table. The SECR will include such a statement in the Working Procedure, adding that such new issues could be discussed only when they are critical for the approval and/or for fulfilling the exclusion or substitution criteria;

- One member pointed out that it should be clarified in the documents whether the Agency refers to the dossier manager, SECR or the Agency in general. The SECR will clarify this;

- One member pointed out that restricting the access to the BPC interest group in CIRCABC to the BPC members would not be possible as for example WG members will need to have access. The SECR replied that the WG members should indeed have access and it will also be clarified how rapporteurs will have access to documents if an MSCA has not appointed a member to BPC and/or the WGs;

- CEFIC asked the SECR to investigate whether the use of e-mails could be completely avoided and instead have all communications in R4BP and CIRCABC. The SECR indicated that this is indeed the intention and this will also be further clarified and included in the Working Procedure;

- One member asked whether the text on candidates for substitution and the exclusion criteria could be combined in chapter 2.2 in the template for a BPC opinion. The SECR will consider the possibilities to change and clarify the text;

Members were invited to provide any further comments in the dedicated CIRCABC Newsgroup by Friday 12 July. The SECR will modify the documents based on any written comments received and according to the conclusions above and provide them for BPC-3.

Actions:
The SECR to provide for BPC-3 the following documents: process description for the steps before eCA submission of the evaluation to the Agency; criteria for passing or failing the accordance check; a template for the CAR; and a revised template for the BPC opinion.

10.2 Union authorisation

The SECR presented an approach for preparing the working procedure for Union authorisation.

There was general support for the proposed flexible approach, including carrying out a consultation of other MSCAs during the eCA evaluation phase.

In particular, the issues below were discussed.

- Proposed 180 day timeline for the eCA to provide critical technical and scientific issues during the eCA evaluation phase: one member observed that the 180 day timeline would be difficult to accommodate within the national systems and that crucial points could be discussed without following a strict process. The SECR explained that the 180 day timeline was not fixed, but was proposed to strengthen the consultation during the evaluation phase and solve technical and scientific issues before the BPC;
- Submission windows: other members asked for clarification in relation to the submission windows. The SECR explained that the submission windows were proposed as a practical tool to fit the applications for Union authorisation in the schedule for the BPC meetings;
- Comparative assessment and similar conditions of use: one member raised the possibility if needed of identifying a specific timeframe during the evaluation phase by the eCA in which the comparative assessment procedure and the

discussion on similar conditions of use across the Union would take place. The SECR noted that the assessment of whether an active substance is a candidate for substitution is carried out during the active substance approval process. COM explained that further guidance would be developed in relation to the substitution criteria. COM also mentioned that biocidal products containing active substances which are candidates for substitution are not excluded from Union authorisation. However, they would not be good candidates for Union authorisation, due to the likely existence of different conditions of use.

- In addition, it was clarified that for products submitted for the purpose of the Biocidal Products Directive[4] but not completed by 1 September, according to Article 91 of the Biocidal Products Regulation (BPR)[5], the product would be subject to comparative assessment as long as the active substance meets the substitution criteria. Consequently, the assessment of whether an active substance meets the substitution criteria has to be performed;
- A member noted that the 30 day timeline from the acceptance of an application for Union authorisation by the Agency and the validation of the application by the eCA might pose some difficulties as the payment, the completeness check and the validation have to be finalised in 30 days. The SECR agreed to take these aspects into account;
- A member suggested that a check of whether the biocidal product contains an active substance where it was concluded in the approval process that the exclusion and substitution criteria are met, should be performed in the framework of the accordance check carried out by the Agency. The SECR noted this proposal;
- CEPE commented that some aspects of the Union authorisation process might be simplified, for example when the representative product and the requested product are the same in terms of their use. The SECR agreed that in such cases the process might be streamlined.

Actions:

The SECR was to provide the following documents for discussion at BPC-3: a draft working procedure for Union authorisation; a draft template for the product assessment reports; a draft template for BPC opinions. In addition, the SECR was to consider including in the framework of the proposed accordance check, an assessment of whether the exclusion and substitution criteria are met.

10.3 Scientific and technical matters concerning mutual recognition

The SECR presented an approach for the Working Procedure for Scientific and Technical Matters concerning Mutual Recognition. The issues below were discussed.

- COM emphasised that the answer to be given by the BPC in this procedure will depend on the question asked by COM in its referral. For COM, what matters is to know if the biocidal product can be authorised according to the summary of product characteristics (SPC) as proposed by a reference Member State. COM will not ask the BPC, for instance, if an assessment factor of 10 or 100 should be used in an assessment, but will ask if the product can be authorised or not, or what would be the appropriate risks mitigation measure, related to the point of disagreement. Therefore, although the opinion is triggered by scientific and technical matters, the main element for the BPC opinion will be to consider the proposed SPC and the appropriateness of the risk mitigation measures in relation to the point of disagreement. Consequently, the decision taken by COM in accordance with Article 36(3) will be clear on how Member States will finally have to act: grant, refuse to grant or cancel the authorisation or vary its terms and conditions;

[4] Directive 98/8/EC concerning the placing of biocidal products on the market.

[5] Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

- One member asked about the discrepancy between 90 days in Article 37(3) which is less than the 120 days for the delivery of an opinion according to Article 38.

Actions:

Members were invited to reflect on the discrepancy between 90 days in Article 37(3) and 120 days for the opinion forming (Article 38) and provide any further comments in the dedicated CIRCA Newsgroup by Friday 12 July.

The SECR was to prepare a draft working procedure for delivering opinions on scientific and technical matter concerning mutual recognition for BPC-3.

11. Interaction between BPR, CLP and the PBT Expert Group

The SECR presented room document BPC-2-2013-11, that provides an overview of the CLH and PBT status for active substances in the Review Programme, for those active substances included in Annex I of the BPD or for which a rapporteur Member State has submitted the first draft CAR to COM. The table in the document shows that for 11 active substances either a CLH Annex VI for CMRs or a PBT dossier is expected to be submitted.

Actions:

Members were invited to provide any further comments on document BPC-2-2013-11 in the dedicated CIRCABC Newsgroup by Friday 12 July. The SECR to revise document BPC-2-2013-11 based on comments received and including the remaining active substances under evaluation for BPC-3.

11.1 CLH

The SECR presented the CLH procedure of the CLP Regulation[6] and interlinks to the pesticides and the biocides regulations. Even though the processes had not been designed to run in parallel, good alignment of the processes was possible if all parties took proper action. In this context the SECR pointed out that the Committee for Risk Assessment (RAC) can deliver opinions on CLH proposals in a much faster way than the legal deadline of 18 months provided that good quality, consistent and complete CLH dossiers are submitted by MSCAs. Before active substances are submitted for the approval or review process under BPR, it was desirable that RAC opinions on CLH dossiers are finalised. This was especially important for substances that met the BPR's exclusion or the substitution criteria.

During the discussions BPC members questioned whether it is appropriate to delay the approval/review of active substances due to outstanding RAC opinions on CLH dossiers. COM and the SECR replied that due to the high work load of the BPC in other processes, such measures would increase the efficiency, as hazard discussions would be resolved in RAC beforehand. The Chair pointed out that discussion on this issue was also part of the upcoming CA meeting in July.

Actions:

The SECR will provide members a document for BPC-3 with links to websites and manuals that describe the process for submission of CLH dossiers and formats to be used.

11.2 PBT Expert Group

The SECR presented the work and practices of the PBT EG. The PBT EG has been established and mandated with the support of CARACAL to assist the MSCAs to take sound science-based decisions on the PBT and very persistent and very bioaccumulative (vPvB) properties of substances. It was proposed the PBT EG is used to discuss proposals

[6] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

for substances which may meet the criteria for PBT and vPvB properties when preparing an active substance proposal or review.

Some members mentioned their concern that such practice could delay the process of active substance approvals. The Chair replied that consultation with the PBT EG would be similar to current practice under the BPD and added that discussions in the PBT EG would increase reliability and consistency of the interpretation of the data and would support the BPC to conclude more rapidly.

Clarifications were also requested on the documents needed by the subgroup. The SECR indicated that, in practice, they could accept any document (ex: the draft CAR).

Actions:

Members were invited to provide any further comments on the proposal provided in the presentation (in particular on the systematic consultation of PBT EG for potential PBT/vPvB/POP[7] substances and systematic consultation of PBT EG for potential candidates for substitution) in the BPC CIRCABC IG newsgroup by Friday 12 July.

12. Guidance development

The SECR presented the meeting documents BPC-2-2013-10 a & b and invited the views of members on the priorities with regard to guidance development and the proposals to involve the BPC working groups in the development of the guidance which is still under development within the framework of the BPD which is under the responsibility of JRC.

Some members suggested that the involvement of the BPC permanent WGs in the development of the guidance should be limited so that they can focus on their core business – the peer review of dossiers. Instead, BPC Ad Hoc WGs may be used to actively contribute to guidance development. Member State experts may need to address niche areas of guidance which would be then shared with a wider forum of experts. Several members stressed the importance of the current WGs under the BPD to continue to work on the guidance until the BPC Ad Hoc WGs are set up. The SECR also pointed out that guidance development should not hinder the BPC opinion-forming process. In this respect, a distinction needs to be made between working methods applicable to individual dossiers which may need to be agreed upon during the dossier processing and guidance having broader relevance that need to follow the standard ECHA guidance consultation procedure.

Following from this discussion, members agreed on the proposals made in the above mentioned meeting documents subject to several modifications:

- Until the BPC Ad Hoc WG takes over, DRAWG would continue with finalising the guidance documents it has been working on so far and it would be used as a platform to discuss EMA and EFSA activities;

- Until the BPC Ad Hoc WG takes over, HEEG would continue with finalising the guidance documents it has been working on so far;

- The BPC permanent WG on efficacy would be consulted on the guidance related to efficacy listed in the meeting document BPC-2-2013-10b;

- BPC WGs would be involved in the further refinement of other guidance documents and consulted on on-going national projects listed in the meeting document BPC-2-2013-10b, when relevant.

In the margins of the discussion, members enquired about the ECHA procedure for guidance development and how this in future will consider inputs and initiatives of the Member States. The SECR explained that the applicability of the ECHA procedure for guidance development for biocides is under discussion and that it is likely that existing material would be utilised in drafting the guidance. The outcome of the activities would be integrated in the overall procedural or scientific guidance under the BPR.

[7] Persistent organic pollutants

Actions:

The SECR to include the involvement of the working groups on the development of the guidance in their mandates.

Members were invited to provide any further comments on meeting document BPC-2-2013-10b and their views on the prioritisation of the guidance projects in the dedicated CIRCA Newsgroup by Friday 12 July.

13. Agreement of the action points and conclusions

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

14. AOB

No items were discussed.

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Part II - MAIN CONCLUSIONS & ACTION POINTS

(Agreed at the 2nd meeting of BPC)

(29-30 May 2013)

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
2 – Agreement of the agenda	
The agenda was agreed.	**SECR** to upload the agreed agenda to BPC CIRCABC IG as part of the meeting minutes.
4 – Agreement of the draft minutes from BPC-1	
The minutes of BPC-1 were agreed.	**SECR** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website.
5 – Administrative issues	
5.2 ICT and submission of evaluations	
It was agreed that there will be an on-going need to access the information currently available in the CIRCABC IG 'Biocides-TM' and that this information can be available as an archive.	**Members** are invited to provide any further comments in the dedicated CIRCA Newsgroup **by Friday 12 July**. **SECR** to take into account the discussion and any further comments as a basis to draw up the detailed structure of the CIRCABC IGs.
6 – Work programme of the BPC	
There was general support for the approach proposed in BPC-2-2013-02a&b. It was agreed the "backlog" dossiers will be considered in accordance with the Commission's proposed work programme (two Commission documents of the last Biocides Competent Authority meeting) based on priority lists per group of product types. For the detailed work programme a balance will be sought between removing the backlog and dealing with evaluations without unnecessary delay after submission to ECHA. For the detailed work programme the SECR will also consider other mechanisms to increase the overall efficiency, e.g. several active substance evaluations for one product type. Several members expressed concern over not accepting evaluations by ECHA before the CLH and PBT EG processes are finalised.	**Members** are invited to provide any further comments in the dedicated CIRCA Newsgroup **by Friday 12 July**. **SECR** to take into account the BPC discussion, the result of the discussion at the July Biocides CA meeting and any further comments from BPC members and prepare a detailed work programme for the next meeting.
7 – Establishing BPC Working Groups	
The approach and mandates for the BPC WGs proposed in BPC-2-2013-03 was agreed subject to several clarifications of the details of the mandates. It was agreed to continue the work of the current HEEG and DRAWG groups by the	**SECR** to revise mandates and on this basis send out invitations to MSCAs to nominate core members and propose flexible members. **SECR** to reflect further on the need for an ad hoc WG on comparative assessment.

mechanism of BPC Ad Hoc WGs.	**SECR** to prepare a mandate(s) for the work of BPC Ad Hoc WG(s) for the next meeting.
8 – Participation of applicants and stakeholders in the BPC (this item included a closed session)	
Several members recommended the participation of applicants in the BPC and accredited stakeholder organisations (ASOs) in the BPC for Type II processes (in addition to the other processes as described in paper BPC-2-2013-04. It was agreed that critical information should be provided well in advance of the BPC meeting in accordance with the Code of Conduct for Stakeholders. To further clarify this, a specific code of conduct for the participation of applicants should be considered. Alternative mechanisms for the involvement of applicants in the BPC should be considered e.g. virtual participation. The importance was agreed of consultation between the eCA and the applicant after the Working Group and, where relevant ad-hoc follow-up.	**SECR** to incorporate the conclusions into the proposal for the ECHA Management Board in June. **SECR** proposed to include in relevant working procedures consultation between applicants and the eCA after the Working Group stage of the process.
9 – BPC Rules of Procedure (RoPs)	
The revised BPC RoPs were agreed with several modifications included in a new version (revision 2 dated 30 May 2013): 1. Delete the urgent written procedure process (Article 20); 2. Provide sufficient flexibility to allow other persons proposed by the MSCAs to attend BPC WGs instead of the rapporteur (Article 18). One member expressed reservations in relation to Articles 9(5) and 17(2).	**SECR** to forward the agreed RoPs to the ECHA Management Board for approval and to upload revision 2 to CIRCA BC.
10 – Working procedures and templates	
10.1 Approval of active substances	
The approach proposed in documents BPC-2-2013-06, 07, 08 and 09 was agreed subject to providing several additional documents and clarifications as listed in the actions.	**Members** are invited to provide any further comments in the dedicated CIRCA Newsgroup **by Friday 12 July**. **SECR** to provide the following documents: 1. Process description before the evaluation is submitted to ECHA by the eCA. 2. Criteria for passing/failing the accordance check 3. Revised template for the CAR and for the BPC opinion. Additional actions for **SECR**: 4. Consider further inclusions in the Working Procedure to clarify the approach for applications already

	provided before 1 September 2013 5. Removing the rapporteur's name from the opinion 6. Consider whether the listing of endpoints should be included in the opinion and the assessment reports 7. Clarify in the CAR structure that the Doc III level for active substances in the review program does not need to be provided as a IUCLID file and that this is part of the submission of the evaluation by the eCA to ECHA 8. Consider incorporating public consultation of all Assessment Reports submitted by the eCA for the Review Programme in line with Article 16 of Regulation 1451/2007 9. Modify the documents according to detailed comments made during the discussion for BPC-3.
10.2 Union authorisation	
There was general support for the proposed flexible approach, including carrying out a consultation of other CAs during the eCA evaluation phase and the proposal of fitting the first submission for Union authorisation in the schedule for active substance approval.	**Members** are invited to provide any further comments in the dedicated CIRCA Newsgroup **by Friday 12 July.** **SECR to provide:** 1. A draft working procedure for Union authorisation for BPC-3 2. A draft template for product assessment reports for discussion at BPC-3 3. A draft template for BPC opinions for discussion at BPC-3. **Additional actions for SECR:** to consider including in the framework of the proposed accordance check, an assessment of whether the exclusion and substitution criteria are met.
10.3 Scientific and technical matters concerning mutual recognition	
	Members are invited to reflect on the discrepancy between 90 days in Article 37(3) and 120 days for the opinion forming (Article 38) and provide any further comments in the dedicated CIRCA Newsgroup **by Friday 12 July**. **SECR** to prepare a draft working procedure for delivering opinions on type II processes for BPC-3.
11 – Interaction between BPR, CLP and the PBT Expert Group	
11.1 CLP	
	Members are invited to provide any further comments on document BPC-2-2013-11 in the dedicated CIRCA Newsgroup **by Friday 12 July**. **SECR** to revise document BPC-2-2013-11 according to comments received and extend it to all active substances for BPC-3. **SECR** to provide to a document for BPC-3 with links to websites and manuals that describe the

	process for submission of CLH dossiers and formats to be used. Update document BPC-2-2013-11 including the remaining active substances under evaluation for BPC-3.
11.2 PBT Expert Group	
	Members are invited to provide any further comments on the proposal provided in the presentation (in particular on the systematic consultation of PBT EG for potential PBT/vPvB/POP substances and systematic consultation of PBT EG for potential candidates for substitution), Members are invited to provide comments on the table in document BPC-2-2013-11 to the dedicated CIRCA Newsgroup **by Friday 12 July**. **SECR** to update document BPC-2-2013-11 including the remaining active substances under evaluation for BPC-3.
12. Guidance development	
BPC agreed that: 1. Until the BPC Ad Hoc WG takes over this work, DRAWG would continue with finalising the guidance documents it has been working on so far and it would be used as a platform to discuss EMA and EFSA activities 2. Until the BPC Ad Hoc WG takes over this work, HEEG would continue with finalising the guidance documents it has been working on so far 3. The BPC WG on efficacy would be consulted on the guidance related to efficacy listed in the meeting document BPC-2-2013-10b. 4. BPC WGs would be involved in the further refinement of other guidance documents and consulted on on-going national projects listed in the meeting document BPC-2-2013-10b, when relevant. The outcome of the activities would be integrated in the overall procedural or scientific guidance under the BPR.	**Members** are invited to provide comments on meeting document BPC-2-2013-10b and their views on the prioritisation of the guidance projects in the dedicated CIRCA Newsgroup **by Friday 12 July**. **SECR** to include the involvement of the working groups on the development of the guidance in their mandates.
13. Conclusions and action points	
BPC members agreed these main conclusions and action points of BPC-2.	**SECR** to upload the conclusions and action points to the CIRCABC IG after the meeting.

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Part III - List of Attendees

Members
BORGES Teresa (PT)
CZAKÓ Klára Mária (HU)
DONS Christian (NO)
DRAGOIU Simona (RO)
GONZÁLEZ MÁRRQUEZ María Luisa (ES)
GREGG Nicola (UK)
HADJIGEORGIOU Andreas (CY)
HARRISON John (IE)
HEESCHE-WAGNER Kerstin (DE)
IAKOVIDOU Mary (SE)
JANTONE Anta (LV)
LARSEN Jørgen (DK)
MAJUS Saulius (LT)
MERISTE Anu (EE)
PAIRAULT Oliver (FR)
PLATTNER Edmund (AT)
TERNIFI Vesna (SI)
TUUSA Tiina (FI)
VAN BERLO Boris (BE)
ZOUNOS Athanassios (EL)

Alternate
KOMEN Corine (NL)

Observer
TURK Rajka (HR)

Advisers
AZAD Karima (BE)
CHEZEAU Aurelie (FR)
BERTAGNA Pierre-Loic (FR)

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MALM Jukka
MATTHES Jochen
PELTOLA-THIES Johanna
RODRIGUEZ UNAMUNO Virginia
SCHIMMELPFENNIG Heike
SAEZ RIBAS Monica
VAN DE PLASSCHE Erik

Accredited Stakeholder Organisations
BRUYNDONCKX Raf (CEFIC)
DESPREZ Betrand (Eurogroup for Animals)
LEROY Didier (CEPE)
OLEDZKA Gosia (AISE)
REGO Laura (ECEAEE)

Apologies
CAMILLERI Tristan(MT)
JAWORKSA-LUCZAK Barbara (PL)
NELEMANS Maartje (NL)
RUBBIANI Maristella (IT)
ZIGRAND Jeff (LU)

Part IV - List of Annexes

ANNEX I List of documents submitted to the members of the Biocidal Products Committee

ANNEX II Final agenda

ANNEX I

Documents submitted to the members of the Biocidal Products Committee

Number	Title
BPC-A-2-2013	Final draft agenda
BPC-M-1-2013	Draft minutes from BPC-1
BPC-2-2013-01	ICT and submission of evaluations
BPC-2-2013-02a	Work programme of the BPC
BPC-2-2013-02b	Work programme of the BPC (appendix)
BPC-2-2013-03	Establishing working groups
BPC-2-2013-04	Participation of applicants and stakeholders in the BPC
BPC-2-2013-05	Rules of Procedure (RoPs)
BPC-2-2013-06	WP and templates: approval of active substances
BPC-2-2013-07	Structure of the CAR
BPC-2-2013-08	Active substance approval – discussion table template
BPC-2-2013-09	BPC opinion template for active substance approval
BPC-2-2013-10a	Guidance development
BPC-2-2013-10b	Guidance development appendix
BPC-2-2013-11	Overview of CLH and PBT status of active substances in the Review Programme
BPC-2-2013-12	Participation of observers in the BPC - IND comments

ANNEX II

BPC-A-2-2013 FINAL
Agreed at BPC-2
(29 May 2013)

Final agenda

2nd meeting of the Biocidal Products Committee (BPC)

29-30 May 2013
ECHA Conference Centre (Annankatu 18, Helsinki)
29 May: starts at 9:30
30 May: ends at 16:00

Item 1 – Welcome and apologies

Item 2 – Agreement of the agenda

BPC-A-2-2013
For agreement

Item 3 – Tour de table of accredited stakeholder organisations

Item 4 – Agreement of the draft minutes from BPC-1

BPC-M-1-2013
For agreement

Item 5 – Administrative issues

5.1 Housekeeping issues

For information

5.2 ICT and submission of evaluations

BPC-2-2013-01
For discussion

Item 6 – Work programme of the BPC

BPC-2-2013-02
For discussion

Item 7 – Establishing BPC Working Groups

BPC-2-2013-03
For agreement

Item 8 – Participation of applicants and stakeholders in the BPC (this item will include a closed session)

BPC-2-2013-04 & 12

For agreement

Item 9 – Rules of procedure

BPC-2-2013-05

For agreement

Item 10 – Working procedures and templates

10.1 Approval of active substances

BPC-2-2013-06 & BPC-2-2013-07 & BPC-2-2013-08 BPC-2-2013-09

For discussion

10.2 Union authorisation

For discussion

10.3 Scientific and technical matters concerning mutual recognition

For discussion

Item 11 – Interaction between BPR, CLP and the PBT Expert Group

11.1 CLP

For discussion

BPC-2-2013-11

11.2 PBT Expert Group

For discussion

BPC-2-2013-11

Item 12 – Guidance development

BPC-2-2013-10 a & b

For discussion

Item 13 – Agreement of the action points and conclusions

Item 14 – AOB

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