BPC-M-3-2013 FINAL

Agreed at BPC-4

12 February 2014

Final minutes of the 3rd meeting of the Biocidal Products Committee (BPC)

9-10 October 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 third meeting.

The Chair informed BPC members of the participation of 23 members and two alternates. Apologies were received from three members. Three advisers, two representatives of the European Commission, and two accredited stakeholder organisations (ASOs) were present at the meeting.

The Chair announced changes in the composition of the Committee. New members were appointed by France (Pierre-Loic BERTAGNA), the previous member Olivier Pairault had become the alternate, by Luxembourg (Jeff ZIGRAND), and Portugal (Ines MARTINS de ALMEIDA). The member from Portugal Teresa BORGES (PT) had resigned.

The Chair informed BPC members that Malta has appointed Ingrid BUSUTTIL as the new member and Audrey-Anne ANASTASI as an alternate as the member Tristan Camilleri had resigned.

The Chair welcomed Ivana VRHOVAC FILIPOVIC, the new member appointed by Croatia, following its accession to the EU on 1 July 2013.

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 draft agenda (BPC-A-3-2013) and invited any additional items. Two items were proposed to be added to the agenda under AOB: 1) guidance update, 2) authorisation of biocidal products containing already approved active substances fulfilling the exclusion and substitution criteria. The agenda was agreed including the two proposed items.

The list of meeting documents and the final agenda are included in Part IV of these minutes. Two additional meeting documents were tabled as room documents: the revised draft minutes of BPC-2 (BPC-M-2-2013 rev1) and ECHA's Executive Director decision for use of CIRCABC and handling confidential information (BPC-3-2013-16).

3. Agreement of the draft minutes from BPC-2

The revised draft minutes from BPC-2 (BPC-M-2-2013 rev1) were agreed taking into account one of the proposed changes by the Commission. The agreed minutes were to be uploaded to the BPC CIRCABC IG and to the ECHA website after the meeting.

4. Administrative issues

4.1. Housekeeping issues

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

5. Participation of applicants and stakeholders in the BPC

The SECR presented document BPC-3-2013-01 on the participation of applicants and stakeholders in the BPC. The SECR explained that, following the previous meeting, the ECHA Management Board had agreed to the proposal from BPC that applicants should be permitted to participate in BPC Plenary and BPC WG meetings for Type I and II processes. For Type III processes, participation would be decided on a case-by-case basis. However, any new information should be provided well in advance of BPC meetings and a Code of Conduct (CoC) should be drawn up to assist applicants to understand their role and responsibilities.

A draft CoC was included for discussion as an annex to the document BPC-3-2013-01 that included specific provisions concerning submission of new information by applicants. The draft CoC was similar to that which is used for other ECHA Committees.

In addition, to the CoC, document BPC-3-2013-01 proposed principles for managing the participation of accredited stakeholder organisations (ASOs) in future meetings, in the light of the increased number of ASOs that had expressed an interest to participate in the work of the BPC. These principles were intended to ensure a balanced representation of the interests represented by ASOs and that the total numbers of ASOs attending was in proportion to the numbers of BPC members. A revised list of ASOs was annexed to document BPC-3-2013-01 which included the new ASOs that had achieved accreditation status since BPC-2.

A discussion took place on the draft CoC in which members and ASOs from industry expressed their general support for the proposal. However, several members and CEFIC noted that section 3 of the draft should allow sufficient flexibility for applicants to propose the most appropriate representative for BPC or BPC Working Group (WG) meetings and that section 5 will allow applicants to share documents within a task force that have submitted an application. Subject to these modifications the draft CoC was agreed.

Members also agreed to the proposed principles for ASOs attending BPC meetings, namely that the total number of regular ASOs shall not exceed half the number of members; the numbers of regular ASOs representing industry and trade interests and the number representing other interests should be similar; and that where several ASOs representing similar interests wish to participate in BPC meetings, they may be requested to propose a single representative for their grouping. Applying this latter principle, for the revised list of ASOs included in document BPC-3-2013-01, the SECR was requested to approach the three NGOs representing the interests of animal rights organisations.

Actions:

The SECR was to explore with the NGOs listed in document BPC-2013-01 whether consolidation of representation at BPC meetings is possible.

The SECR was to finalise the Code of Conduct for Applicants participating in the BPC and its WGs according to the agreed clarifications and upload to CIRCABC.

6. Work programme of the BPC 2014-2016

The SECR presented documents BPC-3-2013-02a and BPC-3-2013-02b. A third document BPC-3-2013-02c was distributed only to members for information. The SECR described the general work plan for 2014 – 2016 that contains the total number of opinions to be delivered by the BPC per year. The second document presented the detailed work programme containing the names of the active substances and product type combinations and schedules them for the BPC WG and BPC meetings for 2014. The SECR mentioned that the documents still require adjustments to align with the agreed CA meeting documents on the review programme (CA-Sept13-Doc.3.0 – Final and CA-Sept13-Doc8.3 – Final).

Concerning the document BPC-3-2013-02a participants raised the following issues:

- Members noted that some of the estimated numbers of opinions in the document were based on the DG ENV draft revised financial statement dated February 2013, whereas it is clear that the actual number will be different. They were asking ECHA to provide more precise estimates, especially for Union authorisation where no opinions will be required in 2014 because no applications were received so far. One member mentioned that they expect the submission of one draft CAR on a new active substance covering 3 PTs in December, and another one covering also 3 PTs in the spring of 2014. Consequently the number of opinions on new active substances under Article 7 of the BPR will be higher. The SECR explained that some indications of different numbers are available for Union authorisation and scientific and technical matters concerning mutual recognition, however they are highly uncertain and therefore no adjustments to the figures in the financial statement were included. For active substances, members were invited to inform the SECR about any updates they may have on potential applications;
- Members welcomed the Commission outline that the finalised CLH and PBT assessment were not required any longer before submitting the evaluation of an active substance product type combination to ECHA (as a minimum, however the CLP and PBT dossiers must have been submitted to ECHA). A member added, that it might be impossible to wait for the CLH[1] opinion of RAC or the advice from the PBT[2] expert group to be finalised due to the newly established deadlines for submitting evaluations;
- The proposed work programme BPC 2014-2016 (BPC-3-2013-02a) was agreed subject to taking into account the suggested revision of the opinion numbers estimates and adjusting to align with the final CA documents.

Concerning the detailed work programme (BPC-3-2013-02b), the SECR informed members that a public consultation on alternatives must be performed on all active substances (i.e. new and existing active substances of the Review Programme) fulfilling the exclusion or substitution criteria. As the public consultation must be finalised before WG meetings, the SECR proposed to put substances fulfilling the criteria to be discussed at later meetings, so that the public consultation can be set up in time.

Some members reported on the status of their evaluations and explained why some were not yet finalised. Other members confirmed the submission dates and therefore the possibility to discuss their substances at the planned meeting.

Actions:

Members are invited to inform the SECR on foreseen applications for new active substances under the BPR as listed in table 1 in the document (BPC-3-2013-02a).

Members are invited to submit the requested information as listed on the first and the last page in the detailed work programme (BPC-3-2013-02b) by October 25 via the functional mailbox.

SECR to take into account the BPC discussion and prepare further the planning for the BPC and WG meetings for 2014.

7. Establishing BPC Working Groups

7.1. Permanent working groups

The SECR provided a status report on the nominations for core (CMs) and flexible members (FMs) for BPC WGs that had taken place over the summer period. The SECR

[1] Harmonised classification and labelling

[2] Persistent, bioaccumulating and toxic

reported that between seven and nine CMs had been nominated for each of the four per BPC WGs and a total of nearly 120 FMs for the WGs. The distinction between CM and FMs was reiterated and the SECR invited members to consider if they would like to put forward further nominees, particularly for FMs since early nomination will facilitate their involvement in WG meetings.

A number of members sought clarification on various aspects of the way in which the WGs would operate. The SECR clarified these aspects and explained that in addition an information session would take place at the TM IV meeting scheduled to take place in Helsinki on 27 November. However, the SECR agreed to clarify several further aspects: the declarations required for rapporteurs; and the participation of those MSCAs that are not yet members of the BPC in WGs.

Actions:

The SECR to clarify the following aspects:

- The declarations of commitment, confidentiality and interest required for rapporteurs;
- Participation of those MSCAs that are not yet members of the BPC in WGs.

7.2. Ad hoc working groups

The SECR presented document BPC-3-2013-03 which presented draft mandates for two Ad hoc Working Groups supporting the BPC.

The issues below were discussed in relation to the Ad hoc Human Exposure Working Group.

- The procedure for initiating a consultation: several members asked for clarification of the person responsible for forwarding issues to the Group. The SECR clarified that the Chair of the Group will be in charge of this. The Group may be consulted upon request of the Human Health Working Group or of the dossier manager in cooperation with the evaluating Competent Authority during the evaluation phase. The Group could also be consulted during an ad hoc follow up of the WG discussion. In any case, due to the strict timeline of the peer-review processes within the BPC, crucial issues needing a more in-depth investigation should be put forward for the attention of the Group as soon as possible;
- Clarification of the mechanism for communicating the output of the Group: several members sought clarification on the communication channels to report written recommendations and their implementation. The SECR explained that strategies in this regard would be detailed, for example a preliminary agreement on a written recommendation by the Human Health Working Group followed by a BPC agreement could be considered as a possible approach. In addition, webpages will be made available on the ECHA website for the working groups and could be used to publish agreed recommendations. The possibility of opening a CIRCABC site dedicated to the activities of the Ad hoc Human Exposure Working Group to inform when a recommendation is agreed at the BPC is under consideration as well;
- Nomination of members: one member asked when invitations will be sent out to invite nominations of the members of the Group. The SECR confirmed that nominations will be sent out after this meeting;
- Areas of interest: it was noted that the update of the exposure IT tools, in particular the Bayesian Exposure Assessment Tool [BEAT], may be a difficult point to achieve, due to the fact that the IT tools are –usually managed by experts not belonging to the group. The SECR proposed to revise the wording of the point in order to better clarify the potential involvement of the group in this area;

- Identification of the issues currently under consideration by the HEEG[3] for their possible consideration by the ad hoc Human Exposure Working Group: several members stressed that the identification of the open issues currently under consideration within the HEEG would be relevant. The SECR explained that a document is being prepared in this regard with the aim of identifying potential items to be further developed within the Ad hoc Human Exposure Working Group.

The issues below were discussed in relation to the Ad hoc Working Group on the Assessment of Residue Transfer to Food (ARTFood).

- Term of mandate: one member asked why the three year term was not mentioned for this Ad hoc WG, while it was mentioned for the other one. The SECR explained that ARTFood would work on a project basis and was foreseen to be ended when all projects are finalised;
- Amendment of the mandate: the proposal of the SECR was agreed to include within the scope of the Group to contribute to guidance documents on the setting of MRLs[4] prepared by other relevant bodies.

In addition, the establishment of an Ad hoc Working Group on comparative assessment and environmental exposure was discussed. The SECR will consult DG-ENV on the establishment of the ad hoc working group on comparative assessment. The SECR will propose a mandate for an ad hoc working group on environmental exposure for the next BPC meeting.

Actions:

The SECR was to revise the mandate of the Ad hoc Human Exposure Working Group according to the discussion and on this basis send out invitations to MSCAs to nominate members for the two Ad hoc WGs. In addition, the SECR was to propose a mandate for an Ad hoc Environmental Exposure WG for the next meeting and to consider the establishment of an Ad hoc Comparative Assessment WG.

8. Working procedures and templates

The Chair informed the meeting that the SECR would develop two additional working procedures: i) opinions on applications for inclusion in Annex I and review of inclusions of Annex I (Article 75(1)(c)); ii) opinions on request of the Commission or Member States (Article 75(1)(g)). In addition, the Chair informed participants on the use of communication tools between the SECR and the members, stakeholders and applicants: CIRCABC, R4BP 3 and functional mailboxes.

For meeting organisation matters concerning the BPC and the WGs members, stakeholders and applicants were asked to use the functional mailbox biocides-committee-secretariat@echa.europa.eu and a new functional mailbox that will be established for WGs (to be advised after the meeting).

The SECR would appoint a dossier manager (DM) for each application who would act as the contact point between the SECR and the evaluating Competent Authority (eCA).

The SECR had set-up two functional mailboxes which should be used by members, stakeholders and applicants for all communication on active substance approvals and Union authorisation, except formal communication (see below): biocides-bpc-active-substance@echa.europa.eu and biocides-bpc-union-authorisation@echa.europa.eu.

The CIRCABC (Interest Group Biocidal Products Committee) will be used for the distribution of documents by the SECR to the participants of the meeting split into a

[3] Human Exposure Expert Group of the TM

[4] Maximum residue limits

confidential section (accessible for the members) and a non-confidential section (accessible for stakeholders and applicants).

The distribution of evaluations (CARs, PARs and response to comments tables for example) will take place via CIRCABC (Interest Group Biocides TM). The SECR will take over this Interest Group from the Commission. As this Interest Group will contain confidential information, the SECR asked the members to sign a declaration of commitment (room document BPC-3-2013-16). The SECR informed participants that ECHA may in the near future replace CIRCABC by another platform.

The Registry for Biocidal Products version 3.0 (R4BP 3.0) shall be used for formal communication between the SECR, the eCA and the applicant using the "adhoc communication" functionality as described in the respective manuals for industry and authority users. Examples of formal communication are: i) outcome of the validation by the eCA; ii) request for missing information by the eCA during the validation and the submission of this information by the applicant; iii) request for missing information by the eCA during the evaluation and the submission of this information by the applicant. For other communication the functional mailboxes shall be used. Currently, applications for active substance approvals including renewals and applications for Union authorisation could be submitted via R4BP 3.0. The Review Programme and new active substance applications under Article 11 of the Biocidal Products Directive were not yet included in R4BP 3.0. The SECR informed members that it is foreseen to include these applications in the R4BP 3.1 which will be released in the first quarter of 2014. This implies that all communication on the Review Programme and new active substance applications under Article 11 of the Biocidal Products Directive between the SECR, the eCA and the applicants should go via the functional mailbox biocides-bpc-active-substance@echa.europa.eu.

8.1 Approval of active substances

The SECR introduced documents BPC-3-2013-04 (cooperation during the evaluation stage of a biocidal active substance), BPC-3-2013-05 (working procedure for the peer review of biocidal active substance evaluation), BPC-3-2013-06 (template for BPC opinion on active substance approval for submissions by the evaluating CA to ECHA after 1 September 2013), BPC-3-2013-07 (draft CAR template), BPC-3-2013-08 (revised template assessment report for active substance submissions by the RMS to the Commission after 1 September), BPC-3-2013-09 (template for BPC opinion on active substance approval for submissions under the Review Programme by the RMS to COM before 1 September 2013). The issues below were discussed.

8.1 a Working procedure for the peer review (BPC-3-2013-05):

- The SECR clarified that ad hoc communications in R4BP 3 will be sent as attached files which then can be printed, as required by some members;
- As access to CIRCA BC is currently only granted to members of the WGs and the BPC;
- The SECR clarified that the role of the applicant as an observer includes the possibility to provide input to discussions and clarifications to technical or scientific questions where this is requested;
- The SECR confirmed that while the SECR provides the minutes of the WG meetings (including columns c and d), it should be the eCA that provides the input from ad hoc follow-up in columns c and d of the discussion table;
- The SECR confirmed that following the WG meeting, the eCA will need to prepare the updated assessment report, while the SECR will prepare the draft BPC opinion. The SECR-eCA dialogue is needed to ensure aligned documents;

- The possibility was requested to revise the working procedure relatively soon (in approximately 1 year), once experience has been gained by all parties concerned. The SECR confirmed that such revisions were planned to be made as soon as appropriate;
- The SECR clarified that the applicants would in general not be able to submit further information once the CAR has been submitted for peer review to ECHA. The SECR will ensure that the approach is consistent with the Committee for Risk Assessment (RAC).

The following clarifications were to be made in the document:

- The SECR explained the changes needed in the document based on the agreement reached during the September 2013 CA meeting: The exclusion and substitution criteria will need to be assessed for all the CARs, the ones provided before 1 September 2013 and the ones after. The public consultation is also relevant for these relevant CARs, if the exclusion or substitution criteria are fulfilled;
- Further discussion items for the WG are communicated once identified to both the DM and the eCA;
- The study summaries will not need to be transformed into a IUCLID dossier if the application was submitted in the old format before 1 September 2013. The new CAR format concerns the assessment report and conclusions. The IUCLID dossier is not a part of the CAR;
- It is clarified in the definitions that a CAR consists of the assessment report and conclusions;
- A difference between flowcharts for active substance approval and Union Authorisation was pointed out. These differences will be harmonised in the working procedures by the SECR;
- All information submitted during public consultation will be made available to the BPC.

The working procedure for the peer review of biocidal active substance evaluation was agreed subject to the above explained changes to be made in the document.

Actions:

The final document will be provided by 11 November 2013. It was noted that the working procedure shall be revised in the light of experience, for example after one year.

8.1 b *Cooperation during the evaluation stage of a biocidal active substance (BPC-3-2013-04):*

- The SECR explained that this was a living document and a formal agreement would not be necessary as it only concerned the cooperation between the eCA and SECR.
- There was general support for the approach and the way of communication that would be established between the eCA and SECR as proposed in the document.

The following clarifications were to be made in the document:

- Communication between the eCA and DM can take place any time during the evaluation stage, and at the latest at the established intervals of approximately 3 months;
- The text will be clarified with respect to the timing of the 9 months status check and the possible need for preparation time for WG discussions;

- When intending to request for further information, the eCA would consult the DM before making the request if the consequence of the request would be stopping the clock;
- The study summaries will not need to be transformed into a IUCLID dossier if the application was submitted in the old format before 1 September 2013. The new CAR format consists of the assessment report and conclusions and does not include the annotated IUCLID dossier.

The document was agreed subject to the above explained changes to be made in the document.

Actions:

The final document will be provided by 11 November 2013.

8.1 c *Opinion templates (BPC-3-2013-06, BPC-3-2013-09):*

On the opinion template for evaluations submitted before 1 September 2013 the SECR stated that the template would still need to be harmonised with the outcome of the September CA meeting on the principles of decision making for active substances. Following comments from several members, it was agreed that SECR will structure section 2.1 on the conclusions of the evaluation in more detail. It is essential that this section contains all the relevant information for the Standing Committee to take a decision. Consequently, it shall contain more information than the sections 2.3 or 3 of the assessment reports used under the BPD: for example a description on which uses were evaluated, outcome of human health and environment risk assessment etc. The Commission (COM) explained the idea of rationalising and streamlining the relevant documents under the BPR compared to the BPD. Several members stated that the use of the templates leads to IT problems due to the use of different fonts. The SECR will look into this aspect. Following a comment from one member, the peer review process will be incorporated in the process description. On the opinion template for evaluations submitted after 1 September, the SECR indicated that these may have to be split into opinions following applications under the BPR and the BPD.

Actions:

The final document will be provided by 11 November 2013.

8.1 d *CAR template (BPC-3-2013-07):*

- SECR presented the new CAR template, which was tabled to the meeting for discussion.

Members provided the following proposals for adaptations:

- The naming of the sections should be aligned with Annex II and Annex III of the BPR;
- In part D of the CAR, a section covering the confidential part should be included;
- Additional free text fields should be included;
- The section on CLH should be moved in a separate section before section 5 (covering the exclusion and substitution criteria);
- The IT format in the background of the document should be revised since the document is partly not stable.

The commenting period for the new CAR templates ends on 11 November, comments received by then will be considered.

Actions:

The new CAR template will be revised following the comments received during BPC-3 and the commenting period, the final document will be provided for BPC-4.

8.2 Union authorisation

The SECR presented the documents prepared in relation to Union authorisation: BPC-2013-3-10b (Working procedure for the peer review of Union authorisation applications); BPC-2013-3-11 (Template for BPC Opinion on the application for Union authorisation); BPC-2013-3-12 (Structure of the Product Assessment Report). Documents BPC-3-2013-13a (Summary of product characteristics for a biocidal product) and BPC-3-2013-13b (Summary of product characteristics for a biocidal product family) were presented for information.

The issues below were discussed.

Working procedure for the peer review of Union authorisation applications (BPC-2013-3-10b)

- One member asked at which stage of the process and in which document the Member States can raise and report the adjustment of certain conditions of an Union authorisation. The SECR explained that discussions on adjustment of certain conditions should start as soon as the Union authorisation process begins and should take place during the working group discussions and certainly during the BPC meeting. COM added that similar conditions of use should be confirmed during the pre-submission phase before the applicant submits an application for Union authorisation. The details of the process of adjustment conditions of a Union authorisation were still under discussion;
- Another member supported a stronger role of the DM compared to the eCA in coordination and administrative tasks. The SECR agreed to further consider the distribution of tasks between the SECR and the eCA. In addition, COM requested a good coordination between the eCA and SECR during the evaluation phase made by the e-CA, in order to ensure that discussions that will take place later in the BPC can run smoothly. COM asked for a similar process as for the active substance review on the matter;
- One member suggested reviewing the document in light of the experience gained on the process. The SECR supported this proposal.

Structure of the product assessment report (BPC-2013-3-12)

- Some members noticed that the confidential annex was missing. The SECR agreed to include such a confidential annex;
- A member suggested adding a paragraph on similar conditions of use following the pre-submission phase. The SECR agreed to incorporate such a paragraph.

Summary of product characteristics for a biocidal product (BPC-3-2013-13a) and Summary of product characteristics for a biocidal product family (BPC-3-2013-13b)

- One member commented that the same numbering as in Article 22 of the BPR would be desirable in order to clearly identify the origin of the different requirements. The SECR noted this proposal, but mentioned that, as the format for the summary of product characteristics (SPC) was based on the document agreed at the CA meeting, there might be limited possibility for modifying it;
- In relation to the SPC for a biocidal product family, one member asked whether the composition of each product in the family will be specified in the document.

The SECR explained that, in line with discussion at the CA meeting, separate SPCs with details of the composition should be submitted for each individual product of the family.

Actions:

The SECR was to finalise the working procedure for the peer review of Union authorisation applications, the template for a BPC opinion and the structure of the product assessment report according to the discussion. The SECR was to provide for the next BPC meeting a draft template for the product assessment report and a document on cooperation during the evaluation phase.

8.3 Scientific and technical matters concerning mutual recognition

The SECR presented the working procedure for scientific and technical matters concerning mutual recognition (BPC-3-2013-14). No comments were made by the members on the document. The Chair concluded that the meeting agreed the working procedure and that the SECR can finalise the document and publish it on the ECHA web-site.

Actions:

The SECR to finalise and publish the working procedure for delivering opinions on scientific and technical matter concerning mutual recognition.

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

9.1 CLP

The SECR presented the list of the CLH and PBT status of new and existing active substances (BPC-2-2013-11 rev1). Following the BPC-2 meeting, the SECR updated the list with those substances for which the evaluation is on-going in the rapporteur Member State. Members are asked to check and update the list by the indicated deadline of 31 October 2013.

The SECR presented document BPC-3-2013-15 entitled how to prepare and submit a CLH dossier: brief instructions. This document provided a brief manual for the submission of CLH dossiers. The SECR prepared it as a follow-up action of BPC-2. One member enquired which format to use for CLH reports, as ECHA had recently launched a commenting round on a new format. The SECR replied that as the commenting was still on-going, the new format was not final and therefore still may be modified. Once the document is finalised both formats will be accepted during a transitional period. Therefore the preparing competent authority may best decide which format or elements of the formats to use, when preparing new CLH dossiers.

Actions:

Members are invited to provide any further information of the CLH and PBT status of the active substances they are evaluating in the document BPC-2-2013-11 rev1 in the dedicated CIRCA Newsgroup by Thursday 31 October 2013.

The SECR will distribute the revised document BPC-2-2013-11 rev2 for 11 November.

10. Any Other Business

Under this Agenda item two further issues were discussed:

10.1 Guidance update

Following the request of a member concerning the guidance development proposed at the last CA meeting of aggregated exposure and of calculated substance concentration in drinking water at intake points, the SECR gave a preliminary update of the currently on-going guidance developments.

The topics covered were efficacy, dietary risk assessment, disinfection by-products and mixture toxicity. The SECR informed members that the documents were to be discussed at the next TM meeting in November. Topics that would not been finalised at this meeting would move to the newly established Ad hoc Working Groups (see section 7.2).

The list of guidance topics would be revised for the next TM meeting taking into consideration topics mentioned at the last CA meeting.

10.2 Authorisation of biocidal products containing already approved active substances fulfilling the exclusion and substitution criteria

One member drew the attention of the BPC to a document they had prepared for the recent Coordination Group and Biocides CA meetings, but which had only been considered for information. The content of the document described the need for establishing a list of already approved active substances meeting the exclusion or substitution criteria and the need for harmonisation in the Member States on how to authorise biocidal products that contain those active substances. It was proposed in the document that the SECR prepared an overview list of active substances that might fulfil the exclusion and substitution criteria.

The SECR replied that as suggested in the paper, it was preparing a list of active substances highlighting those that potentially fulfil the exclusion and substitution criteria (see item 9.1). Concerning the question on how to deal with the authorisation of products containing such active substances is out of the scope of the BPC, and SECR considered that it should be addressed at the next Biocides CA meeting.

Actions:

SECR to make available the updated priority list as presented in BPC-2 (document BPC-2-2013-10b Guidance development appendix) for guidance to BPC members in advance of TMIV.

11. Agreement of the action points and conclusions

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

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Part II - MAIN CONCLUSIONS & ACTION POINTS

(Agreed at the 3rd meeting of BPC)

(9-10 October 2013)

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
2 – Agreem ent of the agenda	
The agenda was agreed with several AOB items added.	**SECR** to upload the agreed agenda to BPC CIRCABC IG as part of the meeting minutes.
3 – Agreement of the draft minutes from BPC-2	
The revised version of the minutes of BPC-2 was agreed.	**SECR** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website.
5 – Participation of applicants and stakeholders in the BPC	
The principles for the participation of ASOs proposed in document BPC-2013-01 were agreed. The draft Code of Conduct for Applicants participating in the BPC and its WGs was agreed subject to clarifying the following aspects: • Section 3 to ensure the applicant has flexibility to propose the most appropriate representative for each meeting; • Applicant has flexibility to share documents within a task force that have submitted an application.	**SECR** to explore with the NGOs listed in document BPC-2013-01 whether consolidation of representation at BPC meetings is possible. **SECR** to finalise the Code of Conduct for Applicants participating in the BPC and its WGs according to the agreed clarifications and upload to CIRCA BC.
6 – Work programme of the BPC 2014 - 2016	
The work programme for the BPC 2014 – 2016 was agreed subject to minor modifications. A more precise estimation will be included by SECR for Union authorisation and technical and scientific matters concerning mutual recognition.	**Members** are invited to inform SECR on foreseen applications for new active substances under the BPR as listed in table 1 in the document (BPC-3-2013-02a). **Members** are invited to submit the requested information as listed on the first and the last page in the detailed work programme (BPC-3-2013-02b) **by October 25** via the functional mailbox. **SECR** to take into account the BPC discussion and prepare further the planning for the BPC and WG meetings for 2014.
7 – Establishing BPC Working Groups	
7.1 – Permanent working groups	
	SECR to clarify the following aspects: • The declarations required for rapporteurs; • Participation of those MSCAs that are not yet members of the BPC in WGs.

7.2 Ad hoc working groups	
The "Mandates of the Ad hoc Working Groups (Ad hoc WGs) supporting the Biocidal Products Committee (BPC)" (BPC-3-2013-03) were agreed.	**SECR** to: • Revise mandates as agreed; • Send out invitations to MSCAs to nominate members; • Propose a mandate for an Ad hoc Environmental Exposure WG for the next meeting; • Consider the establishment of an Ad hoc Comparative Assessment WG.
8 – Working procedures and templates	
8.0 Overview	
	SECR to alert BPC members when BPC working procedures are published on the ECHA website.
8.1 Approval of active substances	
The document on cooperation during active substance evaluation (BPC-3-2013-04) was agreed subject to minor clarifications to be made in the document. The BPC Working Procedure for the peer review of active substances (BPC-3-2013-05) was agreed subject to minor clarifications to be made in the document. It was noted that the working procedure shall be revised in the light of experience, for example after one year. The revised template for the assessment report for evaluations submitted after 1 September 2013 (BPC-3-2013-08) was agreed subject to inclusion of substitution and exclusion criteria in the document. The new draft template of the CAR (BPC-3-2013-07) was presented. The document is to be revised by SECR following the discussion and a further commenting round and a revised version to be prepared for the next BPC meeting. The SECR will reconsider the opinion templates for active substance approval before the first BPC meeting in 2014 in light of the discussions on the amended Review Regulation 1451/2007 (currently discussed at the Biocides CA meeting). The opinion templates for active substance approval for evaluations submitted before (BPC-3-2013-09) and after (BPC-3-2013-06) 1 September 2013 are to be revised by SECR followed by a final commenting round.	**SECR** to provide the following documents: • Final documents BPC-3-2013-04,05 and 08 taking into account the discussion at BPC-3 **by 11 November 2013;** • Document BPC-3-2013-07 taking into account the comments provided during the discussion at BPC-3 and written comments **for the next meeting;** • Revised documents (BPC-3-2013-06 and 09) **by 31 October.** **Members** are invited to provide any further comments on the documents below in the dedicated CIRCA Newsgroups as follows: • BPC-3-2013-06, 07 and 09: **by 11 November.** Additional actions for **SECR**: • To update document BPC-3-2013-05 which relates to evaluations for existing active substances (Review Programme) as follows: 1. Indicate that based on the CA meeting decision, the exclusion and substitution criteria and public consultation concern also CARs submitted before 1 September 2013; 2. Indicate that there is flexibility for using the old CAR template, except for new applications and renewals where the new template would always be required; 3. Clarify that study summaries instead of IUCLID files will be accepted also after 2014; 4. Modify the document according to detailed comments made during the discussion at BPC-3.

8.2 Union authorisation	
The Working Procedure for the peer review of Union authorisation applications (BPC-2013-3-10b) was agreed subject to minor modifications. It was noted that the working procedure shall be revised in the light of experience. The Template for a BPC opinion on an application for a Union authorisation (BPC-2013-3-11) was agreed subject to minor modifications. The Structure of the Product Assessment Report (PAR) (BPC-2013-3-12) was agreed subject to minor modifications. The Summary of product characteristics for a biocidal product (BPC-3-2013-13a) and the Summary of product characteristics for a biocidal product family (BPC-3-2013-13b) were presented for information. SECR informed that these templates will be translated in all EU and EEA languages.	**SECR to provide:** • Final documents BPC-2013-3-10b, 11 and 12 reflecting the discussion at the BPC-3 • A draft template for the PAR for the next meeting; • A document on cooperation during the evaluation phase for the next meeting. **SECR** to further consider the distribution of tasks between ECHA and the eCA
8.3 Scientific and technical matters concerning mutual recognition	
The Working Procedure in document BPC-2013-14 was agreed.	**SECR** to finalise and publish the working procedure.
9 – Interaction between BPR, CLP and the PBT Expert Group	
9.1 CLP	
	Members are invited to provide any further information of the CLH and PBT status of the active substances they are evaluating in the document BPC-2-2013-11rev1 in the dedicated CIRCA Newsgroup **by Thursday 31 October 2013**. **SECR** to distribute the revised document BPC-2-2013-11rev2 for **11 November**.
10 AOB	
10.1 Guidance	**SECR** to make available the updated priority list for guidance to BPC members in advance of TMIV.
11 – Conclusions and action points	
BPC members agreed these main conclusions and action points of BPC-3.	**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
ALMEIDA Ines (PT)
CZAKÓ Klára Mária (HU)
DONS Christian (NO)
DRAGOIU Simona (RO)
GONZÁLEZ MÁRRQUEZ María Luisa (ES)
GREGG Nicola (UK)
HARRISON John (IE)
HEESCHE-WAGNER Kerstin (DE)
IAKOVIDOU Mary (SE)
JANTONE Anta (LV)
LARSEN Jørgen (DK)
MAJUS Saulius (LT)
MERISTE Anu (EE)
NELEMANS Maartje (NL)
BERTAGNA Pierre-Loic (FR)
PLATTNER Edmund (AT)
RUBBIANI Maristella (IT)
TERNIFI Vesna (SI)
TUUSA Tiina (FI)
VAN BERLO Boris (BE)
VRHOVAC FILIPOVIC Ivana (HR)
ZIGRAND Jeff (LU)
ZOUNOS Athanassios (EL)
Alternate
CHROBAK Robert (PL)
GAVRIEL Alexandros (CY)
Advisers
AZAD Karima (BE)
CHEZEAU Aurelie (FR)
KOMEN Corine (NL)
Commission
CHATELIN Ludovic
KILLIAN Karin

ECHA Staff
AIRAKSINEN Antero
BARMAZ Stefania
BUCHANAN Camilla
FABREGA CLIMENT Julia
HOLLINS Steve
HONKANEN Jani
JANOSSY Judit
JONES Stella
KENIGSWALD Hugues
KNIGHT Derek
KREBS Bernhard
MALM Jukka
MATTHES Jochen
MYOHANEN Kirsi
RODRIGUEZ IGLESIAS Pilar
RODRIGUEZ UNAMUNO Virginia
PAKARINEN Mia
PECORINI Chiara
SCHIMMELPFENNIG Heike
VAN DE PLASSCHE Erik
Accredited Stakeholder Organisations
BRUYNDONCKX Raf (CEFIC)
OLEDZKA Gosia (A.I.S.E)
Apologies
BUSUTTIL Ingrid (MT)
HADJIGEORGIOU Andreas (CY)
JAWORKSA-LUCZAK Barbara (PL)

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-3-2013	Draft agenda
BPC-M-2-2013 rev1 (Room document)	Draft minutes from BPC-2
BPC-3-2013-01	Code of conduct for applicants
BPC-3-2013-02 a&b BPC-3-2013-02c (members only)	Work program BPC 2014 – 2016
BPC-3-2013-03	Mandate for ad hoc working groups: Human Exposure and Dietary Risk Assessment
BPC-3-2013-04	Approval of active substances: Cooperation during the evaluation stage of a biocidal active substance
BPC-3-2013-05	Approval of active substances: working procedure for the peer review of biocidal active substance evaluation
BPC-3-2013-06	Approval of active substances: template for BPC opinion on active substance approval for submissions by the evaluating CA to ECHA after 1 September 2013
BPC-3-2013-07	Approval of active substances: template CAR
BPC-3-2013-08	Approval of active substances: revised template Assessment Report for active substance submissions by the RMS to the Commission after 1 September
BPC-3-2013-09	Approval of active substances: template for BPC opinion on active substance approval for submissions under the Review Programme by the RMS to COM before 1 September 2013
BPC-3-2013-10 a&b	Union authorisation Cover note & working procedure for the peer review of Union authorisation applications.
BPC-3-2013-11	Union authorisation: template for BPC opinion on the application for Union authorisation
BPC-3-2013-12	Union authorisation: structure of the Product Assessment Report (PAR)
BPC-3-2013-13 a&b	Union authorisation: templates for the summary of product characteristics for a biocidal product and for a biocidal product family
BPC-3-2013-14	Mutual recognition: working procedure for opinion on technical and scientific matters concerning mutual recognition
BPC-3-2013-15	How to prepare and submit a CLH dossier: Brief instructions
BPC-3-2013-16 (Room document)	ED decision for use of CIRCA and handling confidential information

ANNEX II

BPC-A-3-2013 FINAL
Agreed at BPC-3
(9 October 2013)

Final agenda
3rd meeting of the Biocidal Products Committee (BPC)

9-10 October 2013
ECHA Conference Centre (Annankatu 18, Helsinki)
9 October: starts at 13:30
10 October: ends at 16:00

Item 1 – Welcome and apologies

Item 2 – Agreement of the agenda

BPC-A-3-2013
For agreement

Item 3 – Agreement of the draft minutes from BPC-2

BPC-M-2-2013
For agreement

Item 4 – Administrative issues

4.1 Housekeeping issues

For information

Item 5 – Participation of applicants and stakeholders in the BPC

BPC-3-2013-01
For agreement

Item 6 – Work programme of the BPC 2014-2016

BPC-3-2013-02 a & b
BPC-3-2013-02c (members only)
For agreement

Item 7 – Establishing BPC Working Groups

7.1 Permanent working groups

For information

7.2 Ad hoc working groups

BPC-3-2013-03

For agreement

Item 8 – Working procedures and templates

8.1 Approval of active substances

BPC-3-2013-04 & 05 & 06 & 07 & 08 & 09

For agreement

8.2 Union authorisation

BPC-3-2013-10 a & b & 11 & 12 & 13 a & b

For agreement

8.3 Scientific and technical matters concerning mutual recognition

BPC-3-2013-14

For agreement

Item 9 – Interaction between BPR, CLP and the PBT Expert Group

9.1 CLP

BPC-3-2013-15

For information

Item 10 – AOB

10.1 Guidance update

10.2 Authorisation of biocidal products containing already approved active substances fulfilling the exclusion and substitution criteria

Item 11 – Agreement of the action points and conclusions

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