BPC-M-4-2014 FINAL

Agreed at BPC-5

8 April 2014

Final minutes of the 4th meeting of the Biocidal Products Committee (BPC)

11-12 February 2014

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chair of the Biocidal Products Committee (BPC), welcomed the participants to the fourth meeting. The Chair introduced the ECHA Secretariat (SECR) and welcomed two new administrative assistants. The Chair informed members that the responsibilities of the former Biocides Unit of ECHA have been divided between Unit B1, Committees Secretariat and Unit D4, Biocides Risk Management. The consequence of this is staffing terms is that the Chair of the BPC and the Secretariat have moved to Unit B1.

The Chair informed BPC members of the participation of 24 members including 3 alternates. One member participated remotely. Five advisers, two representatives of the European Commission, and five accredited stakeholder organisations (ASOs) were present at the meeting. Apologies were received from 4 members and one was absent.

Applicants were also present for their specific substances and the details are provided with the summary record of the discussion for the substances.

The Chair announced changes in the composition of the Committee. New members had been appointed by Austria (Nina SPATNY), following the resignation of the previous member Edmund PLATTNER and Marianne KECK had been appointed as the alternate member.

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 Chairman introduced the draft agenda (BPC-A-4-2013) and invited any additional items. No additional items to the agenda were proposed.

The Chairman informed participants that items 8.2 and 8.3 will be held in closed session owing to the potentially confidential nature of the items. The agenda was agreed on this basis and the final agenda was to be uploaded to the BPC CIRCABC IG as part of the meeting minutes.

Five documents were tabled as room documents: BPC-4-2014-11 - Housekeeping and security; BPC-4-2014-14 - Time schedule for HeiQ BPC opinion; BPC-4-2014-16 - Time schedule for BPC opinion following the Commission's request of 31 Jan 2014 under Article 75(1)(g) of the Biocidal Products Regulation (BPR)[1]; BPC-4-2014-17 – Revised Competent Authority Report (CAR) template; and BPC-4-2014-18 - Revised section 2.3 of the draft opinion on ATMAC. These room documents were to be uploaded to the BPC CIRCABC IG after the meeting.

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

3. Declarations of potential conflicts of interest to the agenda

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

[1] Regulation (EU) No 528/2012.

4. Agreement of the draft minutes from BPC-3

The revised draft minutes from BPC-3 (BPC-M-3-2013_rev 1) were agreed taking into account 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.

5. Administrative issues

The Chairman apologised for difficulties several members had experienced with their travel arrangements and explained that this has been caused by structural changes at the travel contractor. Members were invited to provide feedback to the SECR with any further difficulties they experience in relation to travel arrangements.

The Chair also thanked all those who took part in the satisfaction survey that took place in November 2013.

5.1. Housekeeping issues

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

5.2 Participation of applicants and stakeholders in the BPC

The SECR updated participants on progress with the actions arising at BPC-3 in relation to the participation of ASOs and applicants.

The SECR explained the Code of conduct for applicants participating in the work of the Biocidal Products Committee and its Working Groups (BPC WGs) had been finalised on the basis of the discussion at the last meeting. Its provisions are now applicable and were applied to the participation of applicants in this meeting. It is available in the BPC CIRCABC IG and has been published on the ECHA website.

The SECR also reported that the ASOs representing the interests of animal rights organisations had agreed to consolidate their representation at the BPC and the BPC WGs. Accordingly, Kirsty Reid from Eurogroup for Animals from now on at BPC meetings would also represent the European Coalition to End Animal Experiments and Peta International Science Consortium.

6. Work programme of the BPC 2014

The SECR presented the detailed work programme containing the active substance product type combinations scheduled for the BPC WG and BPC meetings for 2014 and the first meetings for 2015. The following comments were made by members:

- DK requested to await the outcome of the PBT Expert Group in April 2014 for tebuconazole before launching the public consultation;
- FR requested to schedule the assessment of technical equivalence for PHMB also for the WG Human Health and the WG Environment as it is a Tier II assessment. The Chair agreed to this proposal;
- ES requested to postpone AEM 5772 and BIT to a later WG;
- SE stated the scheduling of silver zinc zeolite has to be considered as provisional;
- UK reminded that tralopyril was already discussed at the CA meeting so the anticipated discussion at BPC-5 in April 2014 can be limited to the outstanding issues from this meeting;

- COM suggested indicating in the document if the active substance meets the exclusion criteria and if it is a 'multiple dossier case' (several applicants supporting the same active substance/product-type combination).

One member asked for clarification from ECHA on the responsibilities for the assessment of technical equivalence for several situations like multiple dossiers, second source dossiers submitted to a MSCA before and after 1 September 2013. After some discussion it was decided that the SECR will prepare a document for the next meeting which shall include the relationship with Article 95 and the chemical similarity service provided by ECHA.

CEPE raised their concern that, since the draft evaluation prepared by the eCA is no longer made publicly available as was done under the Biocidal Products Directive (BPD)[2], downstream users are only informed after the approval process on which uses are supported and under which conditions. This will give them insufficient time to prepare for product authorisation. The SECR clarified that the draft evaluation will not be made publicly available according to the draft delegated Commission Regulation which will replace Regulation (EC) No 1451/2007. It was suggested to make the detailed work programme publicly available. The SECR will further investigate this.

Actions:

SECR to:

- Revise the Work Programme in the light of comments made at the meeting. This will include a check on multiple dossiers and exclusion and substitution criteria;
- Prepare a document on the responsibilities for technical equivalence and chemical similarity for the next meeting;
- Consider whether the SECR can publish an extract of the Work Programme on the ECHA website;

Members to provide any further information on intentions by industry to submit applications for approval of new active substances or additional product types via the functional mailbox: biocides-bpc-active-substance@echa.europa.eu.

Members are invited to inform the SECR of any further changes to the Work Programme.

7. Applications for approval of active substances

7.1. Working procedure and templates: update from SECR

The SECR made two proposals for a revised procedure for evaluations of the so-called 'back log dossiers' which are directly discussed at the BPC (i.e. without going through the BPC WGs before): i) the proposal as described under "ad 3" in section 2 of document BPC-4-2014-02, which extends the deadline for submitting the relevant documents to the SECR before the BPC meeting; ii) introducing a 30 day commenting period on draft final CARs and a certain time period for the eCA to incorporate comments made before sending assessment reports and draft opinions to the BPC in line with the working procedure. The meeting supported the second proposal. The SECR noted this will impact the work programme for 2014 as it concerns around 20 active substance product type combinations where discussions will have to be moved to a subsequent BPC meeting to include a commenting round on the draft final CARs.

COM clarified the decision-making process on the application for approval of an active substance product type combination following the submission of a BPC opinion and

[2] EC Directive 98/8.

assessment report. After receiving the adopted opinion, COM will prepare a draft decision on the approval and start the process for its adoption (e.g. initiate its interservice consultation and the WTO notification). After these first steps are finalised, a draft decision will be submitted for voting at the Biocides Standing Committee (SC). Although a second discussion on a draft decision is in principle not excluded, COM stated that the intention is to have only one discussion in the SC followed directly by a vote in the same meeting, in contrast to the situation under the BPD where two discussions always took place. COM reminded participants that, as a consequence, the opinions delivered by the BPC need to be fit for purpose to facilitate the decision-making process.

Actions:

SECR to:

- Implement the proposed approach and prepare a document laying down the timelines and reflect on the consequences for the detailed work programme 2014 and adapt it if considered necessary;
- Further consider how to streamline the information needed for future draft BPC opinions before the next meeting (see also 7.2.1).

7.2. Draft BPC opinion on ATMAC for PT 8

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

As part of the BPC-4 meeting documents, the assessment report (AR) had been uploaded to the confidential BPC CIRCABC site and the draft opinion to the non-confidential BPC CIRCABC site before the meeting.

In addition to the substance-specific discussion, this first discussion on an application for approval of an active substance entailed a number of generic issues which are more widely applicable. Accordingly, the summary record of the discussion for ATMAC product type (PT 8) is divided into generic and substance-specific issues.

7.2.1 Generic issues

In addressing the draft opinion for ATMAC, members considered a number of generic issues. These included: the extent to which a BPC opinion should repeat information in section 2.1 (conclusions of the evaluation) that is provided in the AR and therefore the length of the BPC opinion; the opportunity for members before BPC discussions, to review draft final CARs for the 'back log dossiers' that are discussed at BPC meetings without previously having been considered at BPC Working Groups (BPC WGs); and whether the standard phrase related to that the fact that not all potential uses and exposure scenarios were assessed in the evaluation, should be retained in the approval conditions of the opinion (section 2.3).

On the first of these issues, some members expressed the view that a BPC opinion which consists of only a concise summary would not be sufficient for the purposes of approval by the Commission. Other members however, noted that double work should be avoided in producing opinions and ARs, in which there is a risk that the same information is expressed in a different manner in each document. The Commission clarified that a BPC opinion which is fit for the purpose of considering an approval should be as concise as possible, which includes a brief description of the substance, its properties, the uses assessed and the risks identified, as well as a clear set of approval conditions. COM also noted that extensive descriptions of the hazard, risks and efficacy assessment should be avoided in BPC opinions especially since ARs are published. BPC opinions shall also contain clear conclusions on key criteria for approval (exclusion/substitution criteria etc.).

On the second of these issues, the Chair concurred with the view of members that BPC discussions should be focussed on outstanding issues, following a review by members of the draft final CAR prior to the discussion. On this basis, it was agreed to reflect internally on the scheduling of forthcoming substance discussions in order to allow members to review draft final CARs in advance.

In addition after discussion, it was also agreed that the standard sentence in the approval conditions would be retained in BPC opinions.

7.2.2 ATMAC-specific issues

The rapporteur informed participants that the hazard part of the substance had been discussed and concluded at the Technical Meeting I in 2011 (TM I 2011) and the risk part of the assessment in TM III 2012. The draft final CAR had been uploaded to the CIRCABC TM site in January 2014.

The rapporteur explained that the consideration of this draft opinion should also be seen in the context of another application for approval of the same substance referred to as TMAC. In this respect it was proposed that the BPC does not finalise the opinion on ATMAC until it has considered the future opinion on TMAC, which was anticipated to be in 2015.

It was noted by the rapporteur that according to the evaluation described in the AR the substance does not fulfil the exclusion or substitution criteria stated under Articles 5 and 10 of the BPR.

A discussion took place on the draft opinion in which a number of specific issues were addressed. In particular, in relation to the conclusions of the evaluation (section 2.1) and the proposed approval conditions (section 2.3).

In relation to the conclusions of the evaluation, the specific issues discussed included one member which noted a discrepancy between the reference values based on the dog study in the assessment report and the current draft BPC opinion. Another member noted that the physico-chemical and substance identity sections of the draft opinion require further work to elaborate their contents.

The rapporteur noted these points and reported that the applicant had not yet indicated when a five batch analysis would become available. The applicant commented that it had not yet been possible to give a precise timing of when such a study could be completed, but had experienced difficulties with other similar analyses. The Chair invited the applicant to inform the rapporteur at the earliest possible time when the results of such a study could be made available. In general, industry was urged to provide substance identification information preferably with their initial applications and in any case before the evaluation is submitted by the eCA.

In relation to the proposed approval conditions, several members queried the absence of approval conditions in relation to the treatment of wood in contact with fresh water or used for outdoor constructions; and the practicability of the conditions for the treatment of wood with which children may have direct contact.

On the first of these issues, a revised version of the conditions to include this condition was presented (room document BPC-4-2014-18). On the second issue it was agreed that the condition may require further work before being finalised, but that it woud be retained as a flag until the discussion on TMAC takes place. On this basis, the revised section 2.3 of the draft opinion was agreed in principle.

It was agreed the draft opinion will be considered in parallel with that of TMAC with a view to a combined opinion to be discussed and agreed at the BPC in 2015.

Actions:

SECR to upload room document BPC-4-2014-18 to the BPC CIRCABC after the meeting.

Members to provide comments on the final draft CAR, the AR and the opinion by 4 March 2014 in the dedicated CIRCA BC newsgroup.

Rapporteur to:

- Revise the draft final CAR, the opinion and the AR according to the comments and to send them to SECR;
- Inform SECR when the applicant can provide the five batch analysis.

7.3. Draft BPC opinion on permethrin for PT 8

The Chair welcomed the applicants and their accompanying experts for both active substance product-type combinations, PT 8 and PT 18. The Chair noted that the applicants had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

The AR had been uploaded to the confidential BPC CIRCABC site and the draft opinion as part of the BPC-4 meeting documents to the non-confidential BPC CIRCABC site before BPC-4.

The rapporteur informed participants that the hazard part of the substance had been discussed and concluded at the Technical Meeting I in 2011 (TM I 2011) and the exposure and risk assessment part of the assessment in TM III 2012. The draft final CAR had been uploaded to the CIRCABC TM site in January 2014.

The rapporteur explained that according to the evaluation described in the AR the substance does not fulfil the exclusion or substitution criteria stated under Articles 5 and 10 of the BPR.

7.3.1 Hazard assessment

One member questioned the necessity of classification and labelling (C&L) of a dummy biocidal product in the opinion, as the C&L would change anyway depending on the composition of the 'actual' biocidal product. The Chair explained that the C&L of the representative biocidal product included in the active substance approval application was necessary in order to demonstrate that the requirements for authorisation of this biocidal product are met.

The rapporteur explained that as the criteria for skin sensitisation changed within the Regulation on classification, labelling and packaging (CLP)[3], the assessment did not cover whether the substance fulfils the criteria for skin sensitisation 1A or 1B. The rapporteur suggested clarifying this issue with human health experts.

Some members asked for clarification on the potential persistence of the *cis*-isomer mentioned in the draft opinion, because that could influence the outcome of the P assessment for the substance as a whole. The *cis*-constituent was reported to be present as 25% of the substance. The Chair explained that the discussion on persistency was closed in the environment technical meeting in 2011, and proposed to members to go forward with finalising the opinion on the basis of the results of the discussions. Members agreed with this approach and concluded that the evaluating competent authority (eCA) should send a request for advice to the ECHA PBT Expert Group in order to clarify the P status of the substance.

One member proposed to add in the table for the CLP classification the M-factors for the environmental hazards.

A member questioned if the effectiveness of individual isomers had been investigated in relation to the efficacy of the substance as this is important to assess if the criterion

[3] CLP (EC) No 1272/2008.

in Article 10(1)(f) of the BPR is met. Article 10(1)(f) lists the substitution criteria: "it contains a significant proportion of non-active isomers or impurities". The Chair explained that the CA meeting[4] agreed to assess for the on-going review substances specifically the Article 10(1)(a, b and d). Due to the tight timelines this is important for review substances for which the information on isomers might not be available. The Chair mentioned that the applicant is requested to provide a chiral method of analysis for the permethrin enantiomers at product authorisation under point 2.5 of the opinion.

Concerning the control of possible resistance, members questioned the reference to pest control campaigns as, contrary to PT 18 insecticides, the PT 8 wood preservative does not provide for those systems. Members therefore concluded to remove references to codes of good practice in pest control schemes as they are not applicable in PT 8.

7.3.2 Human health risk assessment

The human health risk assessment did not lead to further discussions, except for the consequences of the open skin sensitisation classification. Some members questioned if following the skin sensitisation assessment, the use by non-professionals requires reconsideration. Members concluded that applicants should reconsider non-professional use at product authorisation in light of the new CLP criteria as stated in section 2.4 of the opinion: "elements to be taken into account when authorising products".

COM pointed out the need to reflect on the appropriateness of having, in the proposal for approval, the standard condition related to treated articles as the substance is a skin sensitiser, and pointed out that the approach might need to be revised due to the potential impacts of such condition on the EU market. A member considered that such discussion should rather take place at political level in CA meetings.

7.3.3 Environment risk assessment

The rapporteur reported that the conservative approach taken in the risk assessment resulted in risks in some environmental compartments, for example for soil. These results had in turn impacted on failure of the scenarios for "noise barrier" and for "bridge over pond". The use classes 3a were therefore not considered safe.

Use class 4a however, is safe taking adjustments used for other PT8 substances into account. Members asked the rapporteur to align the CAR, the opinion and the AR following this new outcome.

The rapporteur clarified that that difference in these documents is due to the fact that 100% leaching within one year was used in the original risk assessment due to the missing leaching study. The estimated leaching of 100 % within one year was considered as a conservative value. The risks calculated in this manner during the initial assessment period (named time 1), disappeared when the entire service life is assessed (named time 2). The Chair mentioned that this way forward was also used in other PT 8 active substance approvals.

Members agreed that a leaching test would be mandatory to be submitted at product authorisation.

[4] Document agreed at the CA meeting in September 2013, CA-Sept13-Doc.3.0 – Final, p. 5, https://circabc.europa.eu/w/browse/386abfea-55ce-4764-8a31-f9d4f6ceaf0a

Actions:

Members were invited to provide comments on the draft final CAR, the AR and the opinion by 4 March 2014 in the dedicated CIRCA BC newsgroup.

The Rapporteur to revise the draft final CAR, the opinion and the AR following the comments received and to send them to SECR by 17 March 2014 for uploading before BPC-5.

7.4 Draft BPC opinion on permethrin for PT 18

The Chair informed participants that the applicants for this product type had agreed that the applicants originally intended for only PT 08, could also join the discussion on PT 18. The Chair noted that the applicants had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

The AR was uploaded to the confidential BPC CIRCABC site and the draft opinion as part of the BPC-4 meeting documents to the non-confidential BPC CIRCABC site before BPC-4.

As the hazard part of the substance was already discussed at the PT 8, for PT 18 mainly the human health and the environmental risk assessment and the proposed conditions were further discussed.

Some comments were made on the target species indicated: some were repeatedly mentioned in two following phrases, and others seemed to be more relevant for pesticides than biocides.

7.4.1 Human health risk assessment

Some members mentioned that default values in the assessments were changed, and that explanations for these changes were to be provided. The members were asked to provide these comments in writing so that they can be checked in the respective documents by the rapporteur.

A member asked to limit the mentioned sufficient margins of safety for amateur users to apply only for systemic effects. Due to the potential skin sensitisation, for local effects a reassessment should be performed.

7.4.2 Environment risk assessment

Concerning the PEC/PNEC ratio for the environmental risk assessment, the slightly elevated risk for treatment of textile fibres (just over 1 for service life for sediment) should be further explained in the AR according to members. Members agreed that the overall assessment is conservative and that with the explanations and the appropriate risk mitigation measures, the slight risk could be acceptable.

Some members questioned the applicability of risk mitigation measures and indicated that they will provide their comments after the meeting.

Actions:

Members are invited to provide comments on the final draft CAR, the AR and the opinion by 4 March 2014 in the dedicated CIRCA BC newsgroup.

Rapporteur to revise the draft final CAR, the opinion and the AR following the comments received and to send them to SECR by 17 March 2014 for uploading before BPC-5.

7.5. New Competent Authority report template

The SECR presented the documents BPC-4-2014-04 (amended CAR template), BPC-4-2014-03 (explanatory note) and the room document BPC-4-2014-17 and invited members to provide further input. It was agreed to make changes to the template according to the following proposals:

- The 'ISO name' should be used instead of 'ISO common name' throughout the document;
- A footnote could be added in Chapter 1.3 *Intended uses* to indicate that also uses in treated articles should be given;
- Personal protective equipment should be included also for professional users in Chapter 2.2.1 *Risk characterisation*;
- A heading should be included to give the general conclusion in chapter 4.3.1 *Efficacy*;
- In the table of intended uses (Chapter 4.2), the term 'working mechanism' should be replaced by 'mode of action';
- Separate tables should be included for the different biodegradation studies (especially for higher tier studies) since the headings of the studies may be different;
- In the table provided in chapter 6.2.4 on terrestrial organisms, birds and mammals should be taken out and included in the table in chapter 6.2.6 for primary and secondary poisoning since the endpoints are used to derive the PNEC oral and not the PNEC soil. Bees however will remain in table 6.2.4;
- The example on the 'P' conclusion in the PBT assessment should be deleted as the presented conclusion was considered to be incorrect.
- For industrial applications in Chapters 10.3 and 14.3, the oral exposure was suggested to be deleted as not applicable;
- It should be mentioned that some endpoints like dermal absorption and leaching data are product related data.

The data that would need to be considered as confidential should be included in a confidential annex as publication of CARs will then be possible without a significant amount of work to screen for confidentiality issues.

The SECR clarified that there would be flexibility in using the template, e.g. tables coming directly from the applicants could still be used and would not need to be put in the new format. In the near future, the approach to the format of the documents should be as flexible as possible. From January 2015, the new template should in principle be used for the CARs to be submitted, although there would still be flexibility with regard to e.g. parts of CAR that have already been prepared already and would not need to be transferred into the new format. The same flexibility would apply for substances evaluated earlier where a new product type would then need to be evaluated and parts of the old CAR could directly be used.

Actions:

SECR to: provide the final document BPC-4-2014-04 taking into account the discussion at BPC-4 before BPC-5.

SECR to update document BPC-4-2014-04 as follows:

- Include the revisions requested by members during BPC-4
- Highlight product related data in the list of endpoints.

8. Requests according to Article 75(1)(g) of the BPR

8.1. Draft framework for handling requests according to Article 75(1)(g) of the BPR

The draft framework set out in document BPC-4-2014-05 rev1 was introduced by the SECR and members and COM were thanked for their comments which had been incorporated into the document.

A discussion took place on the document, focusing on several key issues. Firstly some members (DK, FI, FR, NL and SE) as well as COM disagreed with the proposed

approach in the paper that a BPC member should act as a rapporteur or co-rapporteur for each of these requests. Instead, it was suggested that ECHA could act as the rapporteur for some requests, as appropriate.

The SECR explained that the BPC Rules of Procedure are unambiguous and specify*: "For cases pertaining to Article 75(1) (g) of Regulation (EU) No 528/2012 the Committee shall appoint one of its members as a rapporteur…*" (Article 17(3)). In turn, this originates from Article 75(4) of the BPR. Nevertheless, ECHA will take a full and active approach to assist rapporteurs to carry out their role.

COM proposed several additions to the document which were agreed:

- The justification for an urgent request should come from requester (section 1);
- Public consultations to be carried on a case-by-case basis.

Action:

SECR to modify the text as discussed and upload the final version of the framework to CIRCA BC and publish it on the ECHA website.

8.2. HeiQ AGS-20

The SECR introduced the request and work plan (BPC-4-2014-12 & 13 restricted documents), a time schedule (BPC-4-2014-14) for the BPC opinion and proposed one of its members as the rapporteur for the BPC opinion in relation to this request. The time schedule and the proposal for the rapporteur were agreed. The SECR clarified that the applicant may participate in future meetings of the BPC.

Actions:

SECR to provide the rapporteur with the appointment documentation. Rapporteur to prepare the first draft BPC opinion **by 3 March** to the SECR.

8.3. COM request of 31 January 2014

The SECR introduced the request (BPC-4-2014-15 restricted document), a time schedule (document BPC-4-2014-16) for the BPC opinion and proposed one of its members as the rapporteur for the BPC opinion in relation to this request. The time schedule and the proposal for the rapporteur were agreed. SECR clarified that the potentially involved applicant will be included in the consultation on the draft BPC opinion.

Actions:

SECR to provide the rapporteur with the appointment documentation. Rapporteur to prepare the first draft BPC opinion **by 28 February** to the SECR.

9. Establishing BPC working Groups

9.1. Draft mandate for the Ad hoc Working Group on Environmental Exposure and the status of formation of (Ad hoc) Working Groups

The SECR presented document BPC-4-2014-06 rev1, containing the draft mandate for the Ad hoc Environmental Exposure WG supporting the BPC and invited members to provide further input. The following issues were discussed:

Three member states commented that the scope of the Ad Hoc WG should be mainly limited to exposure assessment, one member state preferred to keep the scope wider, including also effect- and risk assessment.

It was concluded that the main focus of the Ad hoc WG will be on environmental exposure. Only on a case by case basis the Ad hoc WG may deal with effects- and risk assessment. In general, if questions related to effect- and risk assessment arise in the Environment WG, these should be solved by a project to which relevant experts - depending on the subject - will be invited to contribute.

Actions:

The SECR to:

- Further emphasise in the document that the main focus of the Ad hoc WG will be on exposure assessment;
- Upload the final version of the mandate to CIRCA BC;
- Invite MSCAs to nominate members.

9.2. Draft project plan ARTFood

The SECR presented the draft project plan of the Ad hoc working group on the Assessment and Transfer of Residues to Food set out in document BPC-4-2014-10. The document was agreed without changes. COM commented that the project plan may need to be revised in light of the outcome of the forthcoming MRL workshop on biocides[5]. The SECR extended the possibility for members to send nominations for ARTFood, if they have not already done so.

Actions:

The SECR to upload the final version of the project plan to CIRCA BC and publish on the ECHA website.

Members were invited to send any further nominations by 28 February 2014.

10. Union authorisation

10.1 Product assessment report (PAR) template

The SECR presented the draft PAR template (BPC-4-2014-07).

BPC members provided the following proposals for adaptations:

- The title of "Section 1" should be "Overall conclusion on the biocidal product";
- The tables should be adapted according to the agreed SPC template;
- In addition to the tables, the inclusion of free text should be allowed, where relevant;
- The sections related to risk assessment for human health and for environment should be aligned in relation to mixture toxicity and substances of concern;
- Confidential information, such as information related to product composition, should be included in a separate annex.

In addition, it was proposed using the PAR template for Union authorisation also for national authorisation, removing the specific elements for Union authorisation. SECR supported this proposal.

Finally, it was suggested that the same PAR template is used by companies for applications for Union authorisation.

[5] European Conference on MRL-Setting for Biocides, Berlin, March 18-19, 2014

CEFIC provided additional comments:

- Duplication of information, such as information on the intended uses, should be avoided;
- It was suggested that information on the applicant and the proposed authorisation holder should be deleted for dissemination purposes;
- Support was expressed in favour of presenting together the effects and the exposure assessment of the active substance(s) and of substance(s) of concern within a biocidal product in the respective chapters.

Actions:

Members are invited to provide any further comments on the document by 7 March 2014.

SECR to:

- Prepare a revised version of the document for the next BPC meeting, taking into account the input received during the discussion;
- Further investigate the use of the template for national authorisation including a consultation with the Coordination Group.

10.2 Cooperation between eCA and ECHA during evaluation stage

SECR presented document (BPC-4-2014-08) which described the individual steps and indicative timelines during the validation and evaluation stages of an application for Union authorisation.

The following clarifications were to be made in the document:

- The sentence under Step 8 "Where the eCA considers that further information is necessary, the eCA should consult the DM before making the request" will be revised in order to be more in line with the legal text;
- Under Step 1, it was suggested adding that ECHA should also check that the application has been submitted in the correct format.

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

Actions:

SECR to provide the final version of document BPC-4-2014-08 taking into account the discussion at BPC-4 before BPC-5**.**

10.3 Approach for pre-submission (BPC-4-2014-09)

The SECR presented the document, which was introduced for information. Clarification was given in response to some members' questions.

11. Agreement of the action points and conclusions

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

12. Any other business

There were no items of any other business.

Part II – Main conclusions and action points

(Agreed at the 4th meeting of BPC)

(11-12 February 2014)

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
2 – Agreement of the agenda	
The agenda was agreed without further additions.	**SECR** to upload the agreed agenda to BPC CIRCABC IG as part of the meeting minutes.
4 – Agreement of the draft minutes from BPC-3	
The revised version of the minutes of BPC-3 was agreed without further changes.	**SECR** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website.
6 – Work programme of the BPC 2014	
Some members commented on the planning for their dossiers. It was agreed that the relevant documents supporting substance discussions are provided according to the relevant timelines in the working procedure.	**SECR** to: • Revise the Work Programme in the light of comments made at the meeting. This will include a check on multiple dossiers and exclusion and substitution criteria; • Prepare a document on the responsibilities for technical equivalence and chemical similarity for the next meeting; • Consider whether the SECR can publish an extract of the Work Programme on the ECHA website; **Members** to provide any further information on intentions by industry to submit applications for approval of new active substances or additional product types via the biocides-bpc-active-substance@echa.europa.eu. **Members** are invited to inform the SECR of any further changes to the Work Programme.
7 – Applications for approval of active substances	
7.1 – Working procedure and templates: update from SECR	
The proposal from the SECR at the meeting to introduce a 30 day commenting period on dossiers finalised at a technical level under the BPD and therefore directly discussed at the BPC was agreed.	**SECR** to: • Implement the proposed approach and prepare a document laying down the timelines and reflect on the consequences for the detailed work programme 2014 and adapt it if considered necessary; • Further consider how to streamline the information needed for future draft BPC opinions before the next meeting.
7.2 Draft BPC opinion on ATMAC for PT 08	
The revised section 2.3 of the draft OPI (room	**SECR to:**

document BPC-4-2014-18) was agreed in principle. The agreed draft OPI will be combined with that for TMAC with a view to a combined OPI to be discussed at the BPC in 2015. It was also agreed that the standard sentences in section 2.3 would be retained in draft BPC opinions. Industry was urged to provide substance identification information preferably with their initial applications and for review programme dossiers at the earliest possible time.	• Upload room document 18 after the meeting; **Members** to provide comments on the final draft CAR, the AR and the opinion **by 4 March 2014** in the dedicated CIRCA BC newsgroup. **Rapporteur to:** • Revise the draft final CAR, the opinion and the AR according to the comments and to send them to SECR; • Inform SECR when the applicant can provide the five batch analysis.
7.3 Draft BPC opinion on permethrin for PT 08	
It was concluded that the PBT Expert Group will be requested by one member to provide advice on the P status of permethrin independent of the adoption of the opinion.	**Members** to provide comments on the final draft CAR, the AR and the opinion **by 4 March 2014** in the dedicated CIRCA BC newsgroup. **Rapporteur** to revise the draft final CAR, the opinion and the AR following the comments received and to send them to SECR by 17 March 2014 for uploading before BPC-5.
7.4 Draft BPC opinion on permethrin for PT 18	
	Members to provide comments on the final draft CAR, the AR and the opinion **by 4 March 2014** in the dedicated CIRCA BC newsgroup. **Rapporteur** to revise the draft final CAR, the opinion and the AR following the comments received and to send them to SECR by 17 March 2014 for uploading before BPC-5.
7.5 New Competent Authority report (CAR) template	
The new draft CAR template was revised following the comments received by the BPC members. The revised new template for the CAR (BPC-4-2014-04) was agreed.	**SECR** to provide the final document BPC-4-2014-04 taking into account the discussion at BPC-4 before BPC-5**;** **SECR** to update document BPC-4-2014-04 as follows: • Include the revisions requested by members during BPC-4 • Highlight product related data in the list of endpoints.
8 – Requests according to Article 75(1)(g) of the BPR	
8.1 Draft framework for handling requests according to Article 75(1)(g) of the BPR	

The draft framework set out in document BPC-4-2014-05 rev1 was agreed subject to including: • Justification for an urgent request should come from requester; • Public consultations to be carried on a case-by-case basis. Five members also wished to be cited in the minutes as proposing that ECHA may act as a rapporteur for these BPC opinions.	**SECR** to modify the text as discussed and upload the final version of the framework to CIRCA BC and publish it on the ECHA website.
8.2 HeiQ AGS-20	
The BPC agreed to appoint one of its members as the rapporteur for the BPC opinion in relation to this request. The time schedule for the opinion development described in document BPC-4-2014-14 was agreed.	**SECR** to provide the rapporteur with the appointment documentation. **Rapporteur** to prepare the first draft BPC opinion **by 3 March** to the SECR.
8.3 COM request of 31 January 2014	
The BPC agreed to appoint one of its members as the rapporteur for the BPC opinion in relation to this request. The time schedule for the opinion development described in document BPC-4-2014-16 was agreed.	**SECR** to provide the rapporteur with the appointment documentation. **Rapporteur** to prepare the first draft BPC opinion **by 28 February** to the SECR.
9 – Establishing BPC Working Groups	
9.1 Draft mandate for Ad hoc Working Group on environmental exposure and status of formation of (Ad hoc) Working Groups	
The mandate of the Ad hoc Working Group for Environmental Exposure supporting the Biocidal Products Committee (BPC) (BPC-4-2014-06 rev1) was agreed. It was concluded that the main focus of the Ad hoc WG will be on environmental exposure. Only on a case by case basis the Ad hoc WG may deal with effects- and risk assessment.	**SECR to:** • Further emphasise in the document that the main focus of the Ad hoc WG will be on exposure assessment; • Upload the final version of the mandate to CIRCA BC; • Invite MSCAs to nominate members.
9.2 Draft project plan ARTFood	
The draft project plan set out in BPC-4-2014-10 was agreed without changes. The project plan may need to be revised in light of the outcome of the MRLs workshop on biocides.	**SECR** to upload the final version of the project plan to CIRCA BC and publish on the ECHA website. Members are invited to send any further nominations by **28 February 2014.**
10 – Union authorisation	
10.1 Product assessment report (PAR) template	

It was suggested to use the template also for national authorisation, removing the specific elements for Union authorisation	**Members** are invited to provide any further comments on the document by **7 March 2014**. **SECR to:** • Prepare a revised version of the document for the next BPC meeting; • Further investigate the use of the template for national authorisation including a consultation with the Coordination Group.
10.2 Cooperation between eCA and ECHA during evaluation stage	
The document on cooperation during the evaluation phase of an application for Union authorisation (BPC-4-2014-08) was agreed subject to minor clarifications to be made in the document.	**SECR** to provide the final document BPC-4-2014-08 taking into account the discussion at BPC-4 before BPC-5**.**
11 – Agreement of the action points and conclusions	
These action points were agreed.	**SECR** to upload the agreed action points and conclusions to CIRCABC after the meeting.

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)
LARSEN Jørgen (DK)
MAJUS Saulius (LT)
MERISTE Anu (EE)
BERTAGNA Pierre-Loic (FR)
SPATNY Nina (AT)
RUBBIANI Maristella (IT)
TERNIFI Vesna (SL)
TUUSA Tiina (FI)
VAN BERLO Boris (BE) (remotely)
VRHOVAC FILIPOVIC Ivana (HR)
ZIGRAND Jeff (LU)
ZOUNOS Athanassios (EL)
HADJIGEORGIOU Andreas (CY)
Alternate
AZDAD Karima (AT)
CHROBAK Robert (PL)
KOMEN Corine (NL)
Advisers
PLATTNER Edmund (AT)
CHEZEAU Aurelie (FR)
KULJUKKA-RABB Terhi (FI)
CRESTI Raffaella (IT)
HUSZAL Sylwester (PL)
Commission
CHATELIN Ludovic
KILLIAN Karin

ECHA Staff
AIRAKSINEN Antero
AJAO Peter
FURHMANN Anna
HOLLINS Steve
JANOSSY Judit
KENIGSWALD Hugues
MATTHES Jochen
PECORINI Chiara
RODRIGUEZ IGLESIAS Pilar
SCHIMMELPFENNIG Heike
VAN DE PLASSCHE Erik
Accredited Stakeholder Organisations
BRUYNDONCKX Raf (CEFIC)
OLEDZKA Gosia (A.I.S.E)
LEROY Didier (CEPE)
STODDART Gilly (PISC)
REID Kirsty (Eurogroup for animals)
Applicants
RAJESH Mathew (Tagros Chemicals India Limited, India) - Permethrin
BLANCQUAERT Jean-Pierre (Tagros Chemicals India Limited, India) - Permethrin
FREEMANTLE Mike (Lonza) - ATMAC
AHLFORD Kristina (Sumitomo Chemicals UK) PLC - Permethrin
THOMAS Jean-Christophe (Bayer S.A.S - Environmental Science) - Permethrin
Apologies
BUSUTTIL Ingrid (MT)
NELEMANS Maartje (NL)
JANTONE Anta (LT)
BARBARA Jaworska (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 for the BPC-4 meeting

Number	**Title**
BPC-A-4-2014	Draft agenda
BPC-M-3-2013 rev1	Draft minutes of BPC-3
BPC/4/2014/01 rev1	Detailed work programme for AS-APP for BPC 2014-15
BPC/4/2014/02	Working procedures and templates: update from SECR
BPC/4/2014/03	Explanatory note to CAR template:
BPC/4/2014/04	CAR template
BPC/4/2014/05 rev 1	Framework for handling Article 75(1)(g) requests of the BPR
BPC/4/2014/06 rev1	Ad hoc working groups: mandate for the Environmental Exposure Ad hoc WG.
BPC/4/2014/07	Union authorisation: PAR template
BPC/4/2014/08	Union authorisation: cooperation during the evaluation stage of Union Authorisation
BPC/4/2014/09	Union authorisation: approach to pre-submission
BPC/4/2014/10	Draft project plan ARTFood
BPC/4/2014/11 ROOM DOCUMENT	Housekeeping and security
BPC/4/2014/12 RESTRICTED	COM request on HeiQ (Article 75(1)(g))
BPC/4/2014/13 RESTRICTED	Draft work plan HeiQ request
BPC/4/2014/14 ROOM DOCUMENT	Time schedule for HeiQ BPC opinion
BPC/4/2014/15 RESTRICTED	COM request of 31 Jan 2014 (Article 75(1)(g))
BPC/4/2014/16 ROOM DOCUMENT	Time schedule for BPC opinion following COM request of 31 Jan 2014
BPC/4/2014/17 ROOM DOCUMENT	Revised CAR template
BPC/4/2014/18 ROOM DOCUMENT	Revised section 2.3 of the draft opinion on ATMAC.

Annex II

BPC-A-4-2014 FINAL
Agreed at BPC-4
11 February 2014

Final agenda
4th meeting of the Biocidal Products Committee (BPC)

11-12 February 2014
ECHA Conference Centre (Annankatu 18, Helsinki)
11 February: starts at 14:00
12 February: ends at 13.30

Item 1 – Welcome and apologies

Item 2 – Agreement of the agenda

BPC-A-4-2014
For agreement

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

Item 4 – Agreement of the draft minutes from BPC-3

BPC-M-3-2013 rev1
For agreement

Item 5 – Administrative issues

5.1 Housekeeping issues

BPC-4-2014-11
(Room document)

5.2 Participation of applicants and stakeholders in the BPC
For information

Item 6 – Work programme for BPC for 2014

BPC-4-2014-01 rev1
For discussion

Item 7 – Applications for approval of active substances

7.1 Working procedure and templates: update from SECR

BPC-4-2014-02
For agreement

7.2 Draft BPC opinion on ATMAC for PT 08

BPC-4-2014-18
(Room document)
For adoption

7.3 Draft BPC opinion on permethrin for PT 08

For adoption

7.4 Draft BPC opinion on permethrin for PT 18

For adoption

7.5 New Competent Authority report (CAR) template

BPC-4-2014-03 & 04
BPC-4-2014-17
(Room document)
For agreement

Item 8 – Requests according to Article 75(1)(g) of the BPR

8.1 Draft framework for handling requests according to Article 75(1)(g) of the BPR

BPC-4-2014-05 rev1
For agreement

8.2 HeiQ AGS-20

- Introduction to the request

BPC-4-2014-12 & 13 (Restricted)
BPC-4-2014-14 (Room document)
For information

- Appointment of the BPC rapporteur

For agreement

8.3 COM request of 31 January 2014

- Introduction to the request

BPC-4-2014-15 (Restricted)
BPC-4-2014-16 (Room document)

For information

- Appointment of the BPC rapporteur

For agreement

Item 9 – Establishing BPC Working Groups

9.1 Draft mandate for Ad hoc Working Group on Environmental Exposure and status of formation of (Ad hoc) Working Groups

BPC-4-2014-06

For discussion

9.2 Draft project plan ARTFood

BPC-4-2014-10

For agreement

Item 10 – Union authorisation

10.1 Product assessment report (PAR) template

BPC-4-2014-07

For discussion

10.2 Cooperation between eCAs and ECHA during evaluation stage

BPC-4-2014-08

For discussion

10.3 Approach for pre-submission

BPC-4-2014-09

For information

Item 11 – Agreement of the action points and conclusions

For agreement

Item 12 – AOB

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