1 April 2015
BPC-M-9-2015

Final minutes of the 9th meeting of the Biocidal Products Committee (BPC)

2 - 6 February 2015

Part I - Summary Record of the Proceedings

1. Welcome and apologies

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

The Chairman informed the participants about the changes to the membership of the BPC: the new German BPC member, Stefanie Jäger, and the alternate member, Viola Weinheimer, have been appointed; the new Finnish alternate member, Anna-Maija Hämäläinen, has been appointed.

The chairman also welcomed the new Commission observer, Martinus Nagtzaam.

The Chairman also communicated that Steve Hollins will be leaving the Secretariat and will move to the Agency's Executive Office after this meeting. The Chair thanked Steve for his contribution to the establishment and work of the BPC and wished him success in his new position in the Agency. Steve's tasks will be taken over by Katja Rauhansalo, the new Secretary of the BPC.

The Chair informed BPC members of the participation of 24 members including seven alternates and one invited expert, exceptionally replacing the Swedish member for this meeting.

Fourteen advisers, two representatives of the European Commission and one representative from accredited stakeholder organisations (ASOs) were present at the meeting. Apologies were received from three members, and two ASOs (Cefic and Eurogroup for Animals).

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

2. Agreement of the agenda

The Chair introduced the final draft agenda (BPC-A-9-2015) and invited any additional items.

The agenda was agreed. The final version of the agenda was to be uploaded to the BPC CIRCABC IG as part of the meeting minutes.

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

Three additional meeting documents were tabled as room documents: Open issues tables for Bardap 26 (BPC-9-2015-14C rev1), for medetomidine (BPC-9-2015-15C rev1) and for C(M)IT/MIT (BPC-9-2015-16C).

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

3. Declarations of potential conflicts of interest to the agenda

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

4. Agreement of the draft minutes and review of actions arising from BPC-8

The revised draft minutes from BPC-8 (BPC-M-8-2014_rev 1) were agreed taking into account several editorial modifications.

The Chair updated members on the status of the actions arising from BPC-8 and noted most items had been completed.

One member noted that the published versions of the opinions do not always contain all of the agreed modifications. The SECR confirmed it will pay careful attention to checking that the opinions contain all the agreed modifications.

Actions:

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

5. Administrative issues

5.1 Housekeeping issues

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

5.2 Other administrative issues

The SECR introduced document BPC-9-2015-01 by informing members on the proposed timing and dates for BPC-10, BPC 11 and for 2016. In addition, the SECR indicated after the meeting it will initiate the annual round of renewal of members' declarations of interest and commitment to be completed by the end of February 2015.

Two new ECHA ASOs, The European Do-It-Yourself (DIY) Retail Association (EDRA) and Aqua Europa, had indicated their interest to participate in the work of the BPC. The BPC agreed to allow the two ASOs to participate as sector-specific ASOs.

Actions:

- **SECR**: to update the ASO list on the ECHA web site and in the BPC CIRCABC IG.

6. Work Programme for BPC

6.1 Revised Work Programme

The Chair introduced the revised BPC Work Programme for 2015 – 2016 (BPC-9-2015-01) and informed that the comments received after the previous meeting have been incorporated in the revised version which was published on the website. Some comments submitted late will be included in the following update.

Members were invited to provide their comments to the current version.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) to the SECR by 13 February 2015.
- **SECR**: on the basis of the changes to update the Work Programme on the ECHA web site and in the BPC CIRCABC IG.

6.2 Outlook 2015 – 2016

The SECR provided an updated status overview of: i) new active substance/PT combinations submitted under the BPR; ii) new active substance/PT combinations submitted under the BPD; iii) first priority active substance/PT combinations submitted in the Review Programme; iv) as well as Review Programme: active substance/PT combinations that belong to the "back-log" dossiers. Back-log dossiers are active substance/PT combinations for which the Member State's evaluation was finalised and the first draft CARs had been submitted to the Commission under the old legislation.

Substances/PT combinations are listed in the status overview unless those are already scheduled for future BPC meetings.

The Chair stressed the importance of Member States informing the SECR of the planned submission dates of their first draft CARs for active substances included in the first priority list of the Review Programme Regulation (deadline 31 December 2015). This will enable SECR to plan when to schedule the dossiers into the BPC work programme for 2016.

A member questioned whether an additional BPC meeting should be scheduled for 2016 to overcome the large amount of opinions expected for that year. Currently there are 23 priority active substances and further 30 new active substances expected to be submitted to ECHA.

The chairman clarified that the aim to adopt 50 opinions per year concerns active substances from the Review Programme. Opinions on new active substances would need to be adopted in addition to this. However, an additional BPC meeting for 2016 is currently not foreseen.

The Commission representative stressed again the importance of progressing active substance dossiers in order to fulfil the commonly agreed deadlines in the Review Programme Regulation, in particular for the 1st priority and 2nd priority lists for which deadlines are coming quickly.

Actions:

- **Members** to check the information in the tables for their active substance/PT combinations and inform the SECR of any corrections;
- **Members** to inform the SECR when their evaluations will be submitted for their active substance/PT combinations listed in the annexes to the document 'Outlook 2015-2016' **by 20 February 2015**.
- **SECR:** to include the information provided and to present a revised report at BPC-10.

7. Applications for approval of active substances

7.1 Working procedure and templates: update from SECR

7.1a Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval

The Chair introduced the document (BPC-9-2015-05) mentioning that some changes were made based on the discussions in the previous meeting. A standard phrase with respect to the requirements for further information was included in section 2.5, concerning the six-month period before the date of approval when additional information will have to be submitted.

It was discussed whether the sentence concerning the provision of efficacy data at product authorisation stage (section 2.4) and the one referring to "dummy" products (section 2.5) should be removed. One argument in favour of the removal was that the opinion should reflect the elements which are essential at the product authorisation stage.

It was agreed to remove both these elements in future opinions.

Actions:

- **Members**: to apply the standard phrases in future draft opinions.
- **SECR**: to revise and upload the catalogue to the BPC CIRCABC after the meeting.

7.1b Revision of the BPC working procedure for biocidal active substance approval

The SECR introduced the revised working procedure highlighting the major changes with respect to the previous version discussed at BPC-8.

One member proposed that the CARs submitted before 1 September 2013 should be evaluated and approved on the basis of the BPD principles, taking into account only the necessary elements of the BPR like the exclusion and substitution criteria. It was agreed not to include this in the working procedure but instead a further discussion on the the principles of peer review should be undertaken e.g. at the workshop organised by ECHA on 5 March 2015. The member from Denmark disagreed and requested that this principle be added to the working procedure for CARs submitted before 1 September 2013

One member pointed out the problem of applications where an approval proposal from the eCA changes into a non-approval proposal following discussion and agreement by the WG. In such a case the CAR may need to be revised in a manner not envisaged in the original evaluation because it may be fully acceptable to apply additional risk mitigation measures e.g. the lowering the concentration of the active substance or performing higher tier exposure assessments. In such cases, the applicant would often be willing to provide further information to support these changes e.g. additional efficacy data. This would also require an additional peer review step. As a consequence it would be very difficult to meet the time limit of 270 days for delivery of the BPC opinion. To address this issue, it was proposed that after the agreement of the current working procedure consideration should be given as to whether a step could be added between the WG and the BPC to handle the difficulties of revising the CAR at a late stage following the WG discussion. This could involve 2 forms of consultation depending on the nature of the WG discussions: the formal ad hoc follow-up process already in place for complex issues where significant changes to the CAR are required; or, a more simple post-WG e-consultation to ensure the conclusions of the WG meeting have been adequately addressed in the revised CAR.

Another possibility mentioned was to have an early WG discussion on the effects assessment before finalising the CAR.

With regard to the submission of additional efficacy data, one member was doubtful if a re-evaluation with a lower concentration would make sense because the efficacy requirements for active substance approval are not very strict while for the product authorisation real efficacy would be required; it would in principle be possible to find a safe concentration for any active substance if the efficacy requirements are too relaxed.

The distinction was discussed between inviting WG core members and applicants and not inviting other members to the WG meetings (steps 12 and 13). SECR will clarify whether the distinction is necessary or whether all members could be invited.

One Member pointed out that the Assessment Report has to be disseminated and that confidential information should be managed appropriately, at first by the applicant. The Commission representative highlighted that some requests to access the public version of the finalised assessment report have already been made by companies, and in that context, the Commission representative re-instated its request that the assessment report should be published by ECHA at the same time as the BPC opinion. In addition, the Assessment Report should be made from the beginning by the evaluating CA taking into account confidentiality aspects, to enable ECHA to disseminate it at the same time as the BPC opinion.

Several members, as well as the Commission representative, stressed the important role of ECHA and the ECHA dossier manager in trilateral discussions and in the finalisation stage of the CAR, as well as in ensuring that the documents are received in time. SECR agreed that the dossier manager as well as the other ECHA experts should play a role in assuring consistency and taking into account the agreements, but it would not be possible with the current resources to systematically check the CARs. SECR noted that the current timeline does not allow for a proper check to be done on the CAR because there is only one week to do this. The proposal in the draft working procedure was agreed, i.e. it is up to each commenting MSCA to ensure that all the agreements in the RCOM are carried over to the updated CAR.

Actions:

- **SECR:** to publish the revised version of the BPC Working Group procedure and the document indicating the revised timelines on the ECHA website and upload them to the BPC CIRCABC IG after the meeting.
- **SECR:** to consider the wider issues at the forthcoming workshop on 5 March 2015.

7.2 Draft BPC opinion on hydrogen peroxide for PT 1, 2, 3, 4, 5 and 6

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

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

- Specification, where it was agreed to modify the threshold value of the content of hydrogen peroxide and the impurity profile regarding heavy metals.
- Efficacy, where it was agreed to add more detailed information both in the AR and in the Opinions.
- Classification, where it was agreed to use the current classification for hydrogen peroxide based on Annex VI of the CLP.
- Resistance, where additional information will be added to the AR.

The AR was agreed subject to the minor modifications described in the open issues table. The following key issues were discussed and agreed with regards the opinion:

- The need to consider a re-entry period for PT2 and PT3 for the specific use conditions. It was agreed that for PT2 it may be considered relevant, whereas for the intended use in PT3 no re-entry period is required.

- The need to add a reference to Regulation 98/2013 on the marketing and use of explosives precursors.
- National limits for drinking water and the need to include a provision for its use in PT5.

The BPC adopted by consensus its opinion on an application for the approval of hydrogen peroxide in use of PT 1, 2, 3, 4, 5 and 6. One member abstained from the adoption of the BPC opinion on PT 2.

Actions:

- **Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 19 March 2015.
- **SECR**: to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR**: to forward the adopted opinion to COM by 26 February 2015 and publish it on the ECHA website.

7.3 Draft BPC opinion on triflumuron for PT 18

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

The Chairman introduced the active substance by indicating that it was discussed in two BPC meetings in 2014, and that following the last BPC discussions an e-consultation in the Environment Working Group took place on the refinements proposed by the applicant.

The rapporteur explained that for the spraying and watering can application scenarios evaluated, unacceptable risks were identified for several compartments for the substance as well as the metabolites.

Although an acceptable risk was identified for the treatment of manure heaps in poultry farms followed by composting, the refinements proposed by the applicant to achieve this were considered too limited for proposing an approval. To have a safe use, the application of the substance would be limited to once per year, the composting would require a hot phase, and the substance could only be used on arable land and not on grassland: these conditions are considered very restrictive, and it cannot be expected that they will be properly enforced nor represent standard practice by farmers. Therefore, the rapporteur proposed the non-approval of triflumuron.

The applicant made a declaration to express their disagreement related to the non-approval proposal. In particular, the applicant criticised the lack of knowledge of current practices in life stock management and manure handling. The applicant considered that the safe use with one application per year is realistic in a management programme using different substances that act with different mode of actions. The applicant claimed that another active substance was approved in PT 18 with the limitation of one application per year. The applicant added that due to the reduction of insecticide products the effective management of rural hygiene in farms is at risk. Application programmes with alternating applications of different substances are required. However, this is threatened due to non-approval decisions leading to limited availability of effective substances.

The BPC adopted by consensus its opinion for the non-approval of triflumuron as an a active substance in PT 18.

Actions:

- **Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 19 March 2015.
- **SECR**: to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR**: to forward the adopted opinion to COM by 26 February 2015 and publish it on the ECHA website.

7.4 Draft BPC opinion on Bardap for PT 8

The Chair welcomed the applicant and their expert 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.

The rapporteur introduced the draft opinion and assessment report, highlighting the specific approach with respect to the identity of the substance and the status of the substance in relation to it being a candidate for substitution.

During the discussion on the draft assessment report, members identified three key questions: the first was a general point of principle as to whether a systemic risk assessment is necessary if the local health effects such as corrosivity are the primary concern for human health; secondly, to what extent can a read across approach be applied to Bardap 26 for the different environmental compartments; and finally was the reported efficacy testing for Bardap 26 fit-for-purpose?

On the first question it was agreed to include a clear statement that no systemic effects were observed in the absence of local effects in any available study. As the systemic effects were considered to be secondary to the local effects, it was agreed to remove the AEL assessment. It was agreed to consult the WG on the approach as the agreement should be relevant for the QUATs remaining in the review program and for other similar substances for which dossiers were submitted before 1 September 2013, where the key driver of the risk assessment is local toxicity.

Concerning the question on read across, the draft opinion was largely, based upon read across from another quaternary ammonium compound, DDAC that has already been assessed and agreed under the Biocidal Products Directive (BPD). Several members noted that text of the opinion needs to be strengthened to reflect exactly which endpoints have been based upon a read across from DDAC. Other members indicated they did not consider a read across approach acceptable for the environmental compartments sediment and soil.

To address the two questions above and before proceeding further, the BPC agreed to consult the BPC WGs - Human Health and Environment to establish first a list of endpoints (LoEPs) for DDAC that may then be applied to this and other similar substance/PT combinations. This will include the issue of the need for the assessment of systemic effects.

The third question identified by several members was in relation to the basis for the efficacy evaluation presented in the draft opinion. Specifically, the efficacy evaluation had been carried out on a formulated product containing copper, rather than Bardap 26 alone. After discussion, it was agreed not to consult the BPC WG - Efficacy on this issue but instead to accept the basis for the efficacy data that had already been assessed at the Technical Meeting.

Actions:

- **SECR**: to coordinate the consultation with the BPC WGs with a view to a discussion at WG II – 2015 scheduled for 23-27 March and then further discussion at BPC-12 29 September - 2 October.
- **Rapporteur**: to prepare a discussion paper and submit to the SECR by 16 February 2015.

7.5 Draft BPC opinion on medetomidine for PT 21

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.

The rapporteur introduced the medetomidine dossier and described the active substance. The substance is considered a candidate for substitution by meeting two of the criteria for being PBT and by containing a significant proportion of non-active isomers.

The Chair informed about the deviation from the working procedure for this dossier due to the significant changes that needed to be incorporated by the eCA after the ad-hoc follow-up process following the initial WG discussions. Consequently, the BPC discussion had to be scheduled to a later meeting, resulting in a delivery of the opinion after more than 270 days of the receipt by ECHA of the evaluation. The deviation was agreed to be acceptable as it concerns a new active substance and consultations took place with the applicant, the eCA and Commission. However, this case should be considered as an exception.

The AR was discussed. Regarding the request by a member for an analytical method in soil, it was clarified that due to the similarity of the sediment and soil matrix the analytical method for sediment can be used. This will be included in the final CAR together with the request for some further validation information for the analytical method in sediment. A number of calculations and transcription errors were pointed out and will be corrected by the eCA. The type of coverall will be clarified in several sections of the AR.

A member requested the inclusion of their minority position on the toxicological reference values, agreed during the ad hoc follow-up, in the public minutes of the Working Group meeting, available on the ECHA website. Members proposed the rewording of several sentences in Section 1.4.1.5 and a clarification to be included in the LoEP regarding the preliminary dietary risk assessment.

The AR for medetomidine was agreed by the BPC, subject to the changes agreed during the meeting.

Next the BPC discussed the opinion. A member requested to add the details of the PPE in the Summary table in Section 2.1 c) of the opinion and the rewording of sentences in section 2.1 c) for non-professionals and item 2 of Section 2.3.

A member proposed that the authorisation of products for non-professionals should not be allowed, due to the unacceptable risk identified for children touching wet paint and the nature of the effects that formed the basis for the AEL value. The eCA and a member clarified that the effects observed were mild sedative effects; severe sedative effects would only be observed at much higher doses (at least two orders of magnitude) than the worst case exposure scenario. The labelling proposed by the eCA, which is the standard requirement in the approval of antifouling active substances, was therefore agreed by the BPC members sufficient to mitigate the risks identified for children touching wet paint.

A clarification of the absence of an analytical method in soil will be included in Section 2.1a) of the opinion. Regarding the substitution criteria, it was mentioned that the

substance might be considered as very persistent according to the degradation study in sediment. The eCA will check this point and clarify whether the substance is persistent or very persistent in the published opinion.

As agreed in the general discussion for the drafting of the opinions, element 3 in Section 2.4 regarding efficacy will be removed from the opinion. One member suggested removing condition (iv) in Section 2.3 regarding the labelling since this element is already covered by condition 4 of Section 2.3.

The BPC adopted by consensus (with the abstention of one member) its opinion on the application for the approval of the active substance medetomidine for use in PT 21. The substance is considered a candidate for substitution in accordance with Article 10(1)(d) and Article 10(1)(f) of the BPR.

Actions:

- **Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 19 March 2015.
- **SECR**: to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR**: to forward the adopted opinion to COM by 26 February 2015 and publish it on the ECHA website.

7.6 Draft BPC opinion on C(M)IT/MIT for PT 2, 4, 6, 11, 12 and 13

The Chair welcomed the applicants. The Chair noted that the applicants had not objected to the presence of ASOs during the discussion. The session was therefore kept open. Following the introduction of the active substance by the rapporteur, the general issues on the ARs and opinions were presented for discussion.

The SECR drew attention to possible inconsistencies in the derivation of the ADI. However, as the issue was raised at such a late stage and the value does not have an impact on the assessment the value remains unchanged.

The naming of the substance as "reaction mass of 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one (3:1)" was agreed in line with the naming convention used for other substances based on the REACH Guidance on substance identification. The active substance is manufactured as a technical concentrate, the stabilisers and impurities are included in the definition of the substance. Four reference sources, with a minimum purity of 57.9%, will be considered for the specification. The detailed calculations will be clarified in the confidential annex of the CAR, and also a non-confidential explanation of the method for deriving the minimum purity will be presented in an annex to the non-confidential assessment report.

The AR for CMIT/MIT PT6 and PT11 were agreed by the BPC, subject to the changes agreed during the meeting.

For PT6 the following key issues were discussed.

The setting of a concentration limit for use of CMIT/MIT as a preservative in liquid detergents (i.e. a concentration for CMIT/MIT in a treated article) for professional users was discussed. The following considerations were taken into account:

- The exposure assessment did not include a dilution factor for the detergent when added to the water used for dishwashing as such a factor is difficult to derive. The conservativeness of the scenario was noted.

- High potency of sensitisation following skin exposure to CMIT/MIT.
- For this type of professional user, a higher concern was perceived related to wearing of gloves during handling and application of the liquid detergents.
- Skin exposure of professionals during handling and application (e.g. dishwashing), including exposure to the detergent itself, to CMIT/MIT eliciting sensitisation cannot be ruled out and managed by the available RMM (including the use of gloves).
- Detergents for professional use are commonly transported in a concentrated form, which is then diluted further before use. For this concentrated form, which is also a treated article, the concentration of the active may be higher and should not be limited to the concentration limit for sensitisation as in this case appropriate RMM are available. Thus, the concentration limit indicated in the opinion refers to the end-use concentration in the liquid detergent used in the *application* phase and not relevant for mixing and loading.
- It was noted that for liquid detergents the "please use gloves" safety phrase is by default on the product label.
- It was confirmed by the applicant that detergents for professionals *only* are available on the market.

It was concluded that a concentration limit should be set for liquid detergents used in the application phase. For other treated articles intended for professionals that were not assessed, similar considerations on the applicability of PPE during application phase needs to be taken into account.

A member stated that CMIT/MIT for PT6 should be considered as a candidate for substitution based on its potent sensitising properties together with the increased number of reports of sensitised people and elicitation of sensitisation from secondary exposure. Consequently, the member considered that Article 10(1)(e) is fulfilled. The member argued that exposure to treated articles, e.g. to paint splashes containing CMIT/MIT may also occur. Another member supported this proposal. However, the majority of the BPC members were of the opinion that the RMM measures imposed, including setting concentration limits for certain end-use treated articles are sufficient to manage the risks and thus Article 10(1)(e) of the BPR is not fulfilled.

The provision on Specific Migration Limits (SMLs) and Maximum Residue Limits (MRLs) was not considered relevant for PT6. However, a dietary exposure assessment is needed when there is a potential for residues in food. Data on the actual amount of residues of CMIT/MIT on surfaces to demonstrate efficiency of a rinsing step or mass of residue transferred into food after surface cleaning was not considered necessary at this stage, however, the current assessment needs to be refined at product authorisation.

The efficacy data requirement related to the representative product will be clarified in the assessment report.

An additional scenario related to preserved paints and coatings was added to the environmental assessment following the working group discussion. It was noted that this scenario has not been assessed earlier for other substances and that only a tier 1 assessment was performed. When degradation is considered the risks will most likely become acceptable. A member noted that treated articles should be assessed at the active substance approval stage. However, it was agreed that a refined assessment will need to be carried out at product authorisation.

For processing fluids used in the pulp and paper industry, risks related to direct discharge were identified where the dilution of the discharge was not sufficient due to

the low flow rate of the receiving water bodies. At product authorisation applicants are required to demonstrate safe use by refining the assessment e.g. by providing monitoring data.

A member explained that pulp and paper mills are regulated, via IPPC and via national legislation in certain countries, and a permit is almost always required which may contain conditions for releasing chemicals to the receiving water body. The feasibility of demonstrating safe use by the applicant for product authorisation for all their potential use conditions was questioned. It was noted, that for treated articles this would be even more difficult.

Similar uses have been evaluated for PT11 and 12 without proposing a restriction, but ensuring that effluents can be discharged directly to receiving water bodies if risks are acceptable. Communication of this specific risk mitigation measure to the end user was considered difficult for the PT6 use as it relates to treated articles.

The SECR clarified that for PT11, national regulations applying to cooling towers and the IPPC best available techniques were used to establish the dilution factors required in the scenarios. Consequently, if the flow rate of the receiving water body is high enough, sufficient dilution is ensured for releasing chemicals to the receiving surface waters. For preserved products the same mitigation measures may not apply.

The applicants argued that monitoring data may be provided to demonstrate safe use and highlighted that the same continuous release is not expected for products meant to control microorganisms during storage before use (PT6). The eCA agreed that other RMM may be available, yet it was not explored for the present risk assessment.

A member noted that when the permit is issued, the composition of the released effluent is considered regardless of the source, whether it comes from the process or otherwise. Therefore, PT6 should be regulated in the same way as PT11 and PT12. The risk mitigations are applied at each and separate mill and not at the biocidal product authorisation level. At the mill, the permit regulates what can or cannot be released, or whether further treatment is necessary before it is released to the receiving water body. In this case, it is not the product but the treated mixture used in a process that has later a release (generally after in house waste treatment) to the water bodies. It is a very indirect release, with several steps and will be difficult to prove whether safe or not in all cases, e.g the degradation rates will vary case by case, river flow rate varies etc.

A member questioned whether the risk assessment is in the remit of the BPR if use is controlled by an overarching legislation. COM highlighted the importance of the exact wording of measures that are proposed by the BPC, and the importance of considering how a recommendation can be implemented and enforced.

It was noted that only demonstration of safe use by refinement of risk assessment e.g. by monitoring data is required at product authorisation, not risk reduction measures. In the assessment report recommendations will be added how to refine the assessment to demonstrate safe use.

Related to PT11 it was discussed whether treated articles exist on the market for this PT. A member clarified that treated water can be seen as a treated article, yet it is not placed on the market.

The BPC adopted by majority its opinion on an application for the approval of the active substance for PT 6. One member did not support the opinion.

The BPC adopted by consensus its opinion on an application for the approval of the active substance for PT 11.

For PTs 2, 4, 12 and 13 further discussions and adoption of the opinions were postponed to the following BPC meeting.

Actions:

For PT6 and 11:

- **Rapporteur:** to revise the relevant assessment reports in accordance with the discussions in the BPC and submit to the SECR by 19 March 2015.
- **Member:** to provide its minority position on the opinion for PT 6 in writing to the SECR by 13 February.
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM by 26 February and publish it on the ECHA website.

For PTs 2, 4, 12 and 13:

- **SECR**: to consider the most appropriate timing for a further BPC discussion in consultation with the rapporteur.
- **Rapporteur**: to revise the draft opinions according to the discussion at BPC-9 by the deadline for submitting documents for the relevant BPC meeting.

7.7 Draft BPC opinion on Biphenyl-2-ol for PT 1, 2, 3, 4, 6 and 13

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

The rapporteur introduced the dossier. Biphenyl-2-ol was notified as an existing active substance by LANXESS Deutschland GmbH and DOW Benelux B.V. in PT 1, 2, 3, 4, 6 and 13. The applicants notified also sodium 2-biphenylate and potassium 2- biphenylate but no complete dossiers were submitted. In the WG V 2014 discussion it was confirmed that sodium and potassium salts have to be considered as active substances and that the current assessment only covers biphenyl-2-ol.

During the discussion on the Assessment Reports, a clarification regarding the CLH status of the substance was requested. It was explained that the substance is already listed in Annex VI of CLP and the rapporteur will submit a new proposal indicating that the substance would meet the criteria for classification as carcinogenic Cat.2. Regarding the carcinogenicity, a member requested to include an overall conclusion on the mode of action behind the carcinogenicity potential of the substance in the ARs. Moreover, a member requested to include in the ARs their minority position on the assessment factor for AELs derivation, agreed during the ad hoc follow-up. It was agreed that the minority position will be included in the WG minutes and not in the ARs, since the ARs would represent the final results of the peer review process.

Clarifications on the skin sensitising properties of the substance and on the skin irritating potential of the representative product were asked for. The rapporteur remarked that the substance is not a skin sensitiser and that the skin irritation is caused by a co-formulant in the representative product.

A member requested to define the human health toxicity of one metabolite found in ground water (diketohydroxy-compound). The rapporteur clarified that the toxicity for the environment of the metabolite found in ground water was investigated using QSARs

and it was concluded that the toxicity of the parent compound covers the toxicity of the metabolite and that the exposure in the aquatic media could be considered negligible. The metabolite is rapidly degraded in water and the human health exposure via drinking water was considered negligible as well. A qualitative assessment of the toxicity of the metabolite to human health will be included in the ARs to confirm that the toxicity of the parent compound covers the toxicity of the metabolite for human health.

Regarding the environmental risk assessment two critical issues were discussed. The first one regarded the DT50 value for soil for a tier II calculation. It was unclear whether the conclusion of the ENV WG on the revaluation of the DT50 value for tier II calculation was implemented and reflected both in the CAR and in the ARs for all PTs.

The second issue was related to the STP degradation. The tier II approach based on monitoring data has been discussed in the ENV WG, where it was agreed that further data should be included to confirm the approach. After the WG, the applicant provided additional monitoring data to support the tier II approach leading to 99% elimination in the STP. It was agreed to apply the value of 99% elimination in the STP but require further information (STP simulation test) to be submitted six months before the approval of the active substance to support this elimination rate. However, it was pointed out that new data which could significantly influence the outcome of the risk assessment should normally not be requested after WG without having a further review possibility.

Given the uncertainties on the appropriateness of the approach applied by the rapporteur for the environmental risk assessment, the Chair in collaboration with the rapporteur verified whether the worst case tier I calculation for the DT50 value in soil would lead to an acceptable risk for the environment. This showed that the risk for the environment was acceptable only for PT 1, 2 and 13. The BPC members agreed that the environmental risk assessment should be revised for PT 3, 4, 6 and therefore the discussion on these PTs was postponed.

The discussions on the opinion for PT1, 2, and 13 were mainly related to the efficacy. It was clarified that the innate efficacy of the substance has been demonstrated and has been considered sufficient for the purposes of active substance approval. Efficacy against some target organisms was demonstrated for the representative products. Further efficacy tests might be requested at product authorisation phase.

The BPC adopted by consensus its opinions on an application for the approval of the active substance for PTs 1, 2 and 13.

Actions:

For the adopted opinions:

- **Rapporteur:** to revise the assessment report according to previous agreements of the BPC WG - ENV and the discussions at the BPC and submit to the SECR by 19 March 2015.
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM by 26 February and publish it on the ECHA website.
- **SECR:** to inform the Commission about the status (whether these salts are considered as active substances) of the sodium and potassium salts of Biphenyl-2-ol following the Working Group discussions.

For PTs 3, 4, 6:

- **SECR:** to consider the most appropriate timing for a further BPC discussion in consultation with the rapporteur.

- **Rapporteur:** to revise the draft assessment report and opinions according to previous agreements of the BPC WG - ENV and the discussions at BPC-9 by the deadline for submitting documents for the relevant BPC meeting.

8. Any other business

8.1 The attendance and participation of BPC members (closed session)

The Chair noted that no applicants or ASOs were present in the closed session. A document prepared by SECR about the attendance of BPC members at meetings and their participation in the work of BPC was presented. The consistency of certain practices of BPC members has been reviewed vis-à-vis the BPC Rules of Procedure in order to see whether there is scope for improvement.

Actions:

- **SECR:** to approach the relevant members regarding the participation.
- **Members**: to inform SECR if there are any problems in attendance.

9. Agreement of the action points and conclusions

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

Part II – Main conclusions and action points

Agreed on 6 February 2015 at the 9th meeting of BPC

2-6 February 2015

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
Item 2 - Agreement of the agenda	
The final draft agenda was agreed without further changes.	**SECR:** to upload the agreed final agenda to the BPC CIRCABC IG as part of the draft meeting minutes after the meeting.
Item 4 - Agreement of the minutes and review of actions from BPC-8	
The revised version of the minutes of BPC-8 was agreed as proposed subject to several editorial modifications.	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website after the meeting.
Item 5 – Administrative issues	
5.2 Administrative issues and report from other ECHA bodies	
It was agreed to include EDRA and Aqua Europa new stakeholders in the BPC ASO list.	**SECR:** to update the ASO list on the ECHA web site and in the BPC CIRCABC IG. **SECR:** to revise the Opinion template with respect to the substitution and exclusion criteria.
Item 6 - Work programme for BPC for 2014 – 2015	
6.1 Revised Work Programme 2014-2015	
	Members: to send information on any further changes to the Work Programme (WP) to the SECR **by 13 February 2015**. **SECR:** on the basis of the changes to update the WP on the ECHA web site and in the BPC CIRCABC IG.
6.2 Outlook (2015-16)	
	Members: to check the information in the tables for their active substance/PT combinations and inform the SECR of any corrections. **Members**: to inform the SECR when their evaluations will be submitted for their active substance/PT combinations listed in the annexes to the document 'Outlook 2015-2016' **by 20 February 2015**. **SECR:** to include the information provided,

	schedule the substance/PTs in the work programme and present an update at BPC-10.
Item 7 - Applications for approval of active substances	
7.1 Working procedure and templates: update from SECR	
7.1a Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval	
It was agreed to remove the standard phrases on efficacy and dummy products (in section 2.4) as they relate to the evaluated product.	**Members:** to apply the standard phrases in future draft opinions. **SECR:** to check where in the AR template additional information requirements (like requirements for further data on efficacy) on the representative product may be added. **SECR:** to revise and upload the catalogue to the BPC CIRCABC after the meeting.
7.1b Revision of the BPC working procedure for biocidal active substance approval	
The revised working procedure was agreed subject to the changes agreed during the discussion. Several issues were highlighted that will be considered further at the forthcoming workshop or in the relevant BPC WG: • When to accept new data; • Acceptability of a reduction in concentration of the active substance late in the process; • Distribution of invitations to include flexible members and alternate BPC members; • Role of the dossier manager; • Checking the updated CAR before the BPC by e-consultation or by an ad hoc follow-up; • Clarification of terminology – AR/CAR; • Publishing the assessment report at the same time as the final opinions.	**SECR:** to publish the revised version of the BPC Working Group procedure and the document indicating the revised timelines on the ECHA website and upload them to the BPC CIRCABC IG after the meeting. **SECR:** to consider the wider issues at the forthcoming workshop on 5 March 2015.
7.2 Draft BPC opinion on hydrogen peroxide for PT 1, 2, 3 ,4, 5 and 6	
The BPC adopted by consensus its opinions on an application for the approval of these active substance/PT combinations. One member abstained for the BPC opinion on PT 2.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 19 March 2015.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion to COM **by 26 February** and publish it on the ECHA website.
7.3 Draft BPC opinion on triflumuron for PT 18	
The BPC adopted by consensus its opinion for the non-approval of this active substance/PT	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC

combination.	and submit to the SECR **by 19 March 2015.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion to COM **by 26 February** and publish it on the ECHA website.
7.4 Draft BPC opinion on Bardap 26 for PT 8	
After a discussion on the draft assessment report, before proceeding further the BPC agreed to consult the BPC WGs Human Health and Environment to establish a list of endpoints (LoEPs) for DDAC that may then be applied to this and other similar substance/PT combinations. There was also a discussion on whether there is a need to review the basis for the efficacy evaluation. It was agreed not to consult the BPC WG - Efficacy on this issue but instead to accept the basis for the efficacy data that had already been assessed at the Technical Meeting.	**SECR:** to coordinate the consultation with the BPC WGs with a view to a discussion at WG II – 2015 scheduled for 23-27 March and then further discussion at BPC-12 29 September - 2 October. **Rapporteur:** to prepare a discussion paper and submit to the SECR by 16 February 2015.
7.5 Draft BPC opinion on medetomidine for PT 21	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. One member abstained. The substance is considered a candidate for substitution in accordance with Article 10(1)(d) and Article 10(1)(f) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 19 March 2015**. **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion to COM **by 26 February** and publish it on the ECHA website.
7.6 Draft BPC opinion on C(M)IT/MIT for PT 2, 4, 6, 11, 12 and 13	
The BPC adopted by majority its opinion on an application for the approval of the active substance for PT 6. One member did not support the opinion. The BPC adopted by consensus its opinion on an application for the approval of the active substance for PT 11.	For the adopted opinions: **Rapporteur:** to revise the relevant assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 19 March 2015**. **Member:** to provide its minority position on the opinion for PT 6 in writing to the SECR **by 13 February.** **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinions to

For PTs 2, 4, 12 and 13 further discussions and adoption of the opinions are postponed to a later BPC meeting which will be determined after the meeting.	COM **by 26 February** and publish it on the ECHA website. For PTs 2, 4, 12 and 13: **SECR:** to consider the most appropriate timing for a further BPC discussion in consultation with the rapporteur. **Rapporteur:** to revise the draft opinions according to the discussion at BPC-9 by the deadline for submitting documents for the relevant BPC meeting.
7.7 Draft BPC opinion on Biphenyl-2-ol for PT 1, 2, 3, 4, 6 and 13	
The BPC adopted by consensus its opinions on an application for the approval of the active substance for PTs 1, 2 and 13. For PTs 3, 4, 6 further discussions and adoption of the opinions are postponed to a later BPC meeting which will be determined after the meeting.	For the adopted opinions: **Rapporteur:** to revise the assessment report according to previous agreements of the BPC WG - ENV and the discussions at the BPC and submit to the SECR **by 19 March 2015**. **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinions to COM **by 26 February** and publish it on the ECHA website. **SECR:** to inform the Commission about the status (whether these salts are considered as active substances) of the sodium and potassium salts of Biphenyl-2-ol following the Working Group discussions. For PTs 3, 4, 6: **SECR:** to consider the most appropriate timing for a further BPC discussion in consultation with the rapporteur. **Rapporteur:** to revise the draft assessment report and opinions according to previous agreements of the BPC WG - ENV and the discussions at BPC-9 by the deadline for submitting documents for the relevant BPC meeting.
Item 8 Any other business	
8.1 The attendance and participation of BPC members	
	SECR: to approach the relevant members regarding the participation. **Members:** to inform SECR if there are any problems in attendance.

Part III - List of Attendees

Members	NAGTZAAM Martinus (DG SANTE)
BERTAGNA Pierre-Loic (FR)	
COSTIGAN Michael (UK)	**Advisers**
DONS Christian (NO)	CHEZEAU Aurélie (FR)
DRAGOIU Mihaela-Simona (RO)	COLLET GORDON Suzanne (NO)
GONZÁLEZ MÁRQUEZ María Luisa (ES)	GONZÁLEZ Lorena (ES)
HARRISON John (IE)	HYVÄRINEN Tuija (FI)
JÄGER Stefanie (DE)	KARHI Kimmo (FI)
LARSEN Jørgen (DK)	KOMEN Corine (NL)
MERISTE Anu (EE)	LEBLOND Annabelle (FR)
MIKOLASKOVA Denisa (SK)	LÖFBOM Johanna (SE)
NELEMANS Maartje (NL)	PALOMÄKI Jaana (FI)
SPATNY Nina (AT)	PLATTNER Edmund (AT)
TERNIFI Vesna (SL)	RAMOS SCHEGEL Carmen (ES)
TUUSA Tiina (FI)	STENHOUSE David (UK)
VACEK Tomáš (CZ)	VILANOVA Eugenio (ES)
VRHOVAC FILIPOVIC Ivana (HR)	WEINHEIMER Viola (DE)
ZIGRAND Jeff (LU)	
	Accredited Stakeholder Organisations
Alternate members	CAZELLE Elodie (AISE)
AZDAD Karima (BE)	
BROVKINA Julija (LV)	**ECHA Staff**
CHROBAK Robert (PL)	AIRAKSINEN Antero
CRESTI Raffaella (IT)	FURHMANN Anna
GAVRIEL Alexandros (CY)	GUTIERREZ ALONSO Simon
SZÁSZ Attila (HU)	HOLLINS Steve
VAGIAS Vasileios (EL)	JANOSSY Judit
	MATTHES Jochen
Invited expert	NEGULICI Ligia
HAHLBECK Edda (SE)	RAUHANSALO Katja
	RODRIGUEZ UNAMUNO Virginia
European Commission	RUGGERI Laura
CHATELIN Ludovic (DG SANTE)	VAN DE PLASSCHE Erik

Applicants	Apologies
BERENDS Albert (Solvay) for Hydrogen peroxide PTs 1-6	BUSUTTIL Ingrid (MT)
BLONDAZ Pascal (BAYER) for Triflumuron PT 18	MARTINS DE ALMEIDA Ines Filipa (PT)
FREEMANTLE Mike (Lonza) for Bardap 26 PT 8	MAJUS Saulius (LT)
HALL Caroline (Evonik) for Hydrogen peroxide PTs 1-6	BRUYNDONCKX Raf (Cefic)
OHLAUSON Cecilia (I-Tech AB) for Medetomidine PT 21	REID Kirsty (Eurogroup for Animals)
QUÉROU Rodolphe (DOW) for C(M)IT/MIT PT 2, 4, 6, 11, 12 and 13	
SCHOESTER Monika (Thor GmbH) for C(M)IT/MIT PT 6, 11, 12 and 13	
STROECH Kalus (LANXESS) for Biphenyl-2-ol PT 1, 2, 3, 4, 6 and 13	
Experts accompanying applicants	
HINDLE Stuart (accompanying QUÉROU Rodolphe) for C(M)IT/MIT and (accompanying STROECH Klaus) for Biphenyl-2-ol	
LINDBLAD Lena (accompanying OHLAUSON Cecilia) for Medetomidine PT 21	
SCHOLTZ Rudolph (accompanying FREEMANTLE Mike) for Bardap 26 PT 8	
WALTER Bernd (accompanying SCHOESTER Monika) for C(M)IT/MIT PT 6, 11, 12 and 13	

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-9 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2	BPC-A-9-2015	Draft final agenda	
4	BPC-M-8-2014 rev 1	Draft minutes from BPC-7	
5	BPC-9-2015-01	Administrative issues and report from the other Committees	
6.1	BPC-9-2015-02	BPC updated Work Programme	
6.2	BPC-9-2015-03	Outlook (2015-16)	
7.1a	BPC-9-2015-04	Catalogue of specific conditions and elements at the PA stage	
7.1b	BPC-9-2015-05	Revised working procedure for active substance approval	
8.1	BPC-9-2015-06	Attendance of BPC members at meetings and their participation in the work of the BPC	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.2	BPC-9-2015-07A	Hydrogen peroxide PT 1	Draft opinion
	BPC-9-2015-07B		Assessment report
	BPC-9-2015-07C		Open issues
	BPC-9-2015-07D		Email from eCA re: reference specification
7.2	BPC-9-2015-08A	Hydrogen peroxide PT 2	Draft opinion
	BPC-9-2015-07B		Assessment report
	BPC-9-2015-07C		Open issues
7.2	BPC-9-2015-09A	Hydrogen peroxide PT 3	Draft opinion
	BPC-9-2015-07B		Assessment report
	BPC-9-2015-07C		Open issues
7.2	BPC-9-2015-10A	Hydrogen peroxide PT 4	Draft opinion
	BPC-9-2015-07B		Assessment report

	BPC-9-2015-07C		Open issues
7.2	BPC-9-2015-11A	Hydrogen peroxide PT 5	Draft opinion
	BPC-9-2015-07B		Assessment report
	BPC-9-2015-07C		Open issues
7.2	BPC-9-2015-12A	Hydrogen peroxide PT 6	Draft opinion
	BPC-9-2015-07B		Assessment report
	BPC-9-2015-07C		Open issues
7.3	BPC-9-2015-13A_rev2	Triflumuron PT 18	Draft opinion
	BPC-9-2015-13B		Assessment report
	BPC-9-2015-13C		Open issues
	BPC-9-2015-13D		Conclusions of ENV WG e-consultation
7.4	BPC-9-2015-14A	Bardap 26 PT 8	Draft opinion
	BPC-9-2015-14B		Assessment report
	BPC-9-2015-14C		Open issues
	BPC-9-2015-14C_rev1 (room doc)		Open issues rev1
7.5	BPC-9-2015-15A	Medetomidine PT 21	Draft opinion
	BPC-9-2015-15B		Assessment report
	BPC-9-2015-15C_rev1 (room doc)		Open issues
7.6	BPC-9-2015-16A_rev1	C(M)IT/MIT PT 2	Draft opinion
	BPC-9-2015-16B		Assessment report
	BPC-9-2015-16C (room doc)		Open issues
7.6	BPC-9-2015-17A_rev1	C(M)IT/MIT PT 4	Draft opinion
	BPC-9-2015-17B		Assessment report
	BPC-9-2015-16C		Open issues
7.6	BPC-9-2015-18A_rev1	C(M)IT/MIT PT 6	Draft opinion
	BPC-9-2015-18B		Assessment report
	BPC-9-2015-16C		Open issues
7.6	BPC-9-2015-19A_rev1	C(M)IT/MIT PT 11	Draft opinion
	BPC-9-2015-19B		Assessment report
	BPC-9-2015-16C		Open issues
7.6	BPC-9-2015-20A_rev1	C(M)IT/MIT PT 12	Draft opinion

	BPC-9-2015-20B		Assessment report
	BPC-9-2015-16C		Open issues
7.6	BPC-9-2015-21A_rev1	C(M)IT/MIT PT 13	Draft opinion
	BPC-9-2015-21B		Assessment report
	BPC-9-2015-16C		Open issues
7.7	BPC-9-2015-22A	Biphenyl-2-ol PT 1	Draft opinion
	BPC-9-2015-22B		Assessment report
	BPC-9-2015-22C		Open issues
7.7	BPC-9-2015-23A	Biphenyl-2-ol PT 2	Draft opinion
	BPC-9-2015-23B		Assessment report
	BPC-9-2015-22C		Open issues
7.7	BPC-9-2015-24A	Biphenyl-2-ol PT 3	Draft opinion
	BPC-9-2015-24B		Assessment report
	BPC-9-2015-22C		Open issues
7.7	BPC-9-2015-25A	Biphenyl-2-ol PT 4	Draft opinion
	BPC-9-2015-25B		Assessment report
	BPC-9-2015-22C		Open issues
7.7	BPC-9-2015-26A	Biphenyl-2-ol PT 6	Draft opinion
	BPC-9-2015-26B		Assessment report
	BPC-9-2015-22C		Open issues
7.7	BPC-9-201-27A	Biphenyl-2-ol PT 13	Draft opinion
	BPC-9-201-27B		Assessment report
	BPC-9-2014-22C		Open issues

AnnexII

BPC-A-9-2015 FINAL
Agreed at PBC-9
2 February 2015

Final agenda

9th meeting of the Biocidal Products Committee (BPC)

2 – 6 February 2015

ECHA Conference Centre, Annankatu 18, Helsinki

2 February: starts at 10:00
6 February: ends at 13:00

Item 1 – Welcome and apologies

Item 2 – Agreement of the agenda

BPC-A-9-2015
For agreement

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

Item 4 – Agreement of the minutes and review of actions from BPC-8

BPC-M-8-2014
For agreement

Item 5 – Administrative issues

5.1 Housekeeping issues

For information

5.2 Other administrative issues

BPC-9-2015-01
For agreement

Item 6 – Work programme for BPC

6.1 Revised Work Programme

BPC-9-2015-02
For information

6.2 Outlook (2015-16)

BPC-9-2015-03
For discussion

Item 7 – Applications for approval of active substances[1]

7.1 Working procedure and templates: update from SECR

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

BPC-9-2015-04

For information

b) Revision of the BPC working procedure for biocidal active substance approval

BPC-9-2015-05

For agreement

7.2 Draft BPC opinion on hydrogen peroxide for PT 1, 2, 3 ,4, 5 and 6

Previous discussion(s): WG-V-2014

PT 1: BPC-9-2015-07A, B, C
PT 2: BPC-9-2015-08A; BPC-9-2015-07B; BPC-9-2015-07C
PT 3: BPC-9-2015-09A; BPC-9-2015-07B; BPC-9-2015-07C
PT 4: BPC-9-2015-10A; BPC-9-2015-07B; BPC-9-2015-07C
PT 5: BPC-9-2015-11A; BPC-9-2015-07B; BPC-9-2015-07C
PT 6: BPC-9-2015-12A; BPC-9-2015-07B; BPC-9-2015-07C

For adoption

7.3 Draft BPC opinion on triflumuron for PT 18

Previous discussion(s): TM II-2011, TM III-2011, TM II-2012, BPC-6 and BPC-7

BPC-9-2015-13A, B, C, D

For adoption

7.4 Draft BPC opinion on Bardap 26 for PT 8

Previous discussion(s): TM III- 2009

BPC-9-2015-14A, B, C

For adoption

7.5 Draft BPC opinion on medetomidine for PT 21

Previous discussion(s): WG- IV- 2014

BPC-9-2015-15A, B, C

For adoption

7.6 Draft BPC opinion on C(M)IT/MIT for PT 2, 4, 6, 11, 12 and 13

Previous discussion(s): WG-II-2014, WG-V-2014

PT 2: BPC-9-2015-16A, B, C
PT 4: BPC-9-2015-17A, B; BPC-9-2015-16C
PT 6: BPC-9-2015-18A, B; BPC-9-2015-16C
PT 11: BPC-9-2015-19A, B; BPC-9-2015-16C
PT 12: BPC-9-2015-20A, B; BPC-9-2015-16C

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

PT 13: BPC-9-2015-21A, B; BPC-9-2015-16C

For adoption

7.7 Draft BPC opinion on Biphenyl-2-ol for PT 1, 2, 3, 4, 6 and 13

Previous discussion(s): WG-V-2014

PT 1: BPC-9-2015-22A, B, C
PT 2: BPC-9-2015-23A, B; BPC-9-2015-22C
PT 3: BPC-9-2015-24A, B; BPC-9-2015-22C
PT 4: BPC-9-2015-25A, B; BPC-9-2015-22C
PT 6: BPC-9-2015-26A, B; BPC-9-2015-22C
PT 13: BPC-9-201-27A, B; BPC-9-2015-22C

For adoption

Item 8 – Any other business

8.1 The attendance and participation of BPC members

(CLOSED SESSION)
BPC-9-2015-06

For discussion

Item 9 – Agreement of the action points and conclusions

For agreement

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