18 September 2015

BPC-M-11-2015

Final minutes of the 11th meeting of the Biocidal Products Committee (BPC)

15 - 18 June 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 eleventh BPC meeting.

The Chairman mentioned the latest changes in the BPC membership, namely: (i) appointment of new BPC members for Sweden, Slovenia and Hungary – Edda Hahlebeck, Petra Čebašek and Emese Szántó respectively; (ii) appointment of Suzanne Collett Gordon as new Norwegian alternate member; (iii) appointment of BPC member and alternate member for Switzerland, following the invitation to Switzerland to participate in the work of the BPC and of its Working Groups; the appointees are Manuel Rusconi and François Python respectively.

The Chairman also noted that this was going to be the last meeting in which the current Dutch member takes part before her retirement and that she would be replaced by the current alternate member as of August 2015.

The Chairman informed the BPC members of the participation of 25 members, including three alternates.

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

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

2. Agreement of the agenda

The Chairman introduced the final draft agenda (BPC-A-11-2015_rev3) and invited any additional items.

Three additional items were added to the agenda under Item 8, following proposals from members. They were related to (i) the possibility of introduction of new data or information during the peer review process; (ii) the applicability of guidelines and guidance; (iii) the working procedure for active substance approval, more specifically: the timing and format for providing the Draft Final CA report and the open issues documents and ensuring that opinion amendments agreed during the BPC meetings are incorporated prior to the discussion of the final opinions in the Standing Committee on Biocidal Products.

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

The Chairman 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.

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

3. Declarations of potential conflicts of interest to the agenda

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

4. Agreement of the draft minutes and review of actions arising from BPC-10

The revised draft minutes from BPC-10 (BPC-M-10-2015_rev1), incorporating the comments received from members, were agreed.

Under the follow-up of the actions arising from BPC-10, it was communicated to BPC members that the written procedure for the approval of the opinions for peracetic acid PT 1-6 would be launched soon. Concerning the introduction of additional information requirements on the representative biocidal product in the Assessment Report, the Chairman informed that the templates both for the assessment reports and for the opinions would be reviewed over the summer.

On the modalities for proceeding when consensus cannot be reached in the Working Groups, the Chairman reported that following the discussions at the previous BPC meeting, the "concluding procedure for the Working Groups" was presented by the SECR and endorsed in the meetings of the Working Groups in May.

To follow, the Chairman informed the BPC members on the agreement reached at the Coordination Group meeting with reference to the requirement to include residue analytical methods for air for DEET and IR3535 in the dossiers for product authorisation. This data requirement should be fulfilled both for already authorised products (at the product renewal stage) and for new products for which the authorisation is requested (after the renewal date of the relevant active substance).

One member stated it is not stated in the minutes but that at the meeting it was concluded that ECHA would take up to discuss the scenario for the use of disinfectants in PT 3 for footbath disinfection in the Environment Working Group.

Actions:

- **SECR:** to upload the agreed minutes from BPC-10 to the BPC CIRCABC IG and to the ECHA website after the meeting;
- **SECR:** to consider at the Environment Working Group the scenario for the use of disinfectants in PT 3 for footbaths.

5. Administrative issues

5.1 Housekeeping issues

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

5.2 Administrative updates and report from other ECHA bodies

The Chairman introduced document BPC-11-2015-01 covering the report from the other ECHA Committees and provided to members for information purposes.

6. Work Programme for BPC for 2015– 2016

6.1 Revised Work Programme 2015-2016

6.2 Outlook

The Chairman presented the work programme and the outlook. With respect to the Working Group meeting of November 2015, the Chairman informed the members that after internal consultation the SECR considered it feasible to deal with that many dossiers at one meeting (in total more than 30). In addition the Chairman informed the meeting that the SECR will probably re-schedule some dossiers in 2016, to have a more balanced distribution between meetings. The Chairman informed the meeting that ECHA will initiate a project to develop guidance for efficacy for PT 5 and instructions, guidance and a kind of helpdesk construction for all disinfectants. The project will start in the beginning of 2016 and aimed at assisting MSCAs and contribute to enabling to finish the list 2 priority active substance PT combinations in time. With respect to the outlook the Chairman, supported by COM, requested the members to give priority to the list 2 priority substances (PT 3, 4 and 5). If needed, dossiers will have to be prioritised for BPC meetings in the coming year(s). With respect to splitting PTs for the same active substance, one member argued for not splitting as for MSCAs it is considered more efficient to discuss all PTs at the same BPC meeting.

Actions for agenda item 6.1:

- **Members**: to send information on any further changes to the Work Programme (WP) to the SECR by 26 June 2015.
- **SECR**: on the basis of the changes to update the WP on the ECHA web site and in the BPC CIRCABC IG.

Actions for agenda item 6.2:

- **Members**: to check the information in the tables for their active substance/PT combinations and inform the SECR of any corrections **by 31 July 2015**.
- **SECR:** to include the information provided, schedule the substance/PT combinations in the Work Programme and present an update of the outlook at BPC-12.

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 Chairman introduced the document (BPC-11-2015-04) mentioning that no changes were made compared to the previous version distributed for BPC-10. The catalogue will be amended with respect to the wording of conditions on treated articles as soon as an agreement is reached at CA level. The SECR will revise the assessment report and opinion templates based on earlier discussions at the BPC.

Actions:

- **Members:** to apply the standard phrases in future draft opinions.

- **SECR:** to revise and upload the Assessment Report and opinion templates to the BPC CIRCABC IG after the meeting.

7.2 Draft BPC opinion on biphenyl-2-ol for PT 3, 4 and 6

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

SECR noted that the opinions on PT1, 2 and 13 had already been adopted by consensus at BPC-9. Due to environmental issues, product types 3, 4 and 6 were postponed to the current BPC.

The eCA introduced the substance and indicated that some difficulties were encountered for the preparation of the meeting. Above all, the eCA highlighted that the time between the availability of the document in CIRCABC and the BPC meeting is too short and that it would be appreciated if SECR would apply more flexibility in relation to the deadline for uploading the documents on CIRCABC. Finally the eCA suggested to upload the draft BPC opinion with track changes on CIRCABC. SECR noted the comments and the suggestions.

The eCA informed the BPC members that some bilateral discussions took place with SECR and the major point, which has been solved, concerns the AEC dermal that will be removed from the ARs. The BPC has been informed that there have been some consultations on the environmental risk assessment before the meeting, which involved the eCA, DE and SECR. The eCA presented the outcome of the new calculations of the application of the active substance in PT3 on manure/slurry on arable land. It was clarified that the outcome of the consultation would change some conclusions of the environmental risk assessment but one safe use is still identified. Since the eCA provided the revised calculations close to the BPC meeting it wasn't possible for BPC members as well as the applicant to review them. Therefore, it was agreed to evaluate the revised environmental risk assessment via written consultation and to postpone the discussion on PT3 to the December BPC meeting.

The discussion on the other PTs continued.

The members discussed the specificity of the conditions to which the active substance approval is subjected. As a general remark, COM highlighted that so far the conditions strictly reflect the assumptions of the scenario applied for the risk characterisation, while it would be preferable to define more general conditions, as in most cases, elements refer to issues to which attention shall be paid at product authorisation rather than strict restrictions. COM's proposal was supported by several members. The members agreed to provide more general conditions, provided that safe uses and risks would be clearly identified in the opinions. For PT 4, that means, that the majority of the members agreed to restrict the use of large scale disinfection instead of restricting disinfection in slaughterhouses as the risk is a matter of surface area and not a matter of location.

Several members suggested including the MRL provision for PT 6. Due to consistency reasons with other BPC Opinion in PT 6, this provision was not included.

The Assessment Reports for PT 4 and 6 were agreed by the BPC, subject to the changes agreed during the meeting.

The BPC adopted by consensus its opinions on an application for the approval of the active substance for PTs 4 and 6.

Actions:

For PT 4 and 6:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 30 July 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 opinion to COM **by 9 July 2015** and publish it on the ECHA website.

For PT 3:

- **SECR:** to launch an ad-hoc follow up on the environmental risk assessment.
- **SECR:** To schedule the draft BPC opinion on biphenyl-2-ol adoption for BPC-13.

7.3 Confirmation of the conclusions of the combined CAR for DDAC for PT 8

The Chairman welcomed the applicants 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 rapporteur introduced the combined assessment report (AR). The Koc value presented in the combined list of endpoints (LoEP) will be updated based on the result of the ad hoc follow up. The revised Koc value will not influence the outcome of the evaluation.

An ad hoc follow up on the QUATs, in particular ATMAC/TMAC concluded that no unacceptable risk is foreseen for the child entering in direct contact with treated wood. It was agreed that this conclusion sufficiently demonstrates that risks are acceptable for children, therefore, the "unless clause" of the relevant provision is fulfilled and can be referred to at product authorisation.

The combined AR was agreed with the minor changes described in the open issues table. The BPC confirmed the conclusions of the combined assessment report for DDAC.

Actions:

- **Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 30 July 2015**.
- **SECR**: to disseminate the combined assessment report on CICRCA BC and on the ECHA website.

7.4 Confirmation of the conclusions of the combined CAR for ADBAC/BKC for PT 8

The Chairman welcomed the applicants 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 rapporteur introduced the combined assessment report (AR). The Koc value presented in the combined list of endpoints (LoEP) will be updated following the same

approach as has been proposed for DDAC in the ad hoc follow up. The revised Koc value will not influence the outcome of the evaluation.

An ad hoc follow up on the QUATs, in particular ATMAC/TMAC concluded that no unacceptable risk is foreseen for the child entering in direct contact with treated wood. It was agreed that this conclusion sufficiently demonstrates that risks are acceptable for children, therefore the "unless clause" of the relevant provision is fulfilled and can be referred to at product authorisation. COM clarified that, in such situations, there is no need to review the approval conditions for these active substances, as the approval conditions were not blocking product authorisation.

The combined AR was agreed with the minor changes described in the open issues table. The BPC confirmed the conclusions of the combined assessment report for ADBAC/BKC.

Actions:

- **Rapporteur**: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 30 July 2015.
- **SECR**: to disseminate the combined assessment report on CICRCA BC and on the ECHA website.

7.5 Draft BPC opinion on PHMB for PT 1, 2, 3, 4, 6, 9 and 11

The Chairman welcomed the applicant and their expert for this item. The Chairman noted that the applicant objected to the presence of ASOs during the discussion on those elements for which confidentiality was claimed. The session was therefore closed for those elements.

The rapporteur introduced the PHMB (1600; 1.8) dossiers and described the active substance. The substance is considered a candidate for substitution by meeting two of the criteria for being PBT.

Following the introduction of the active substance by the rapporteur, the general issues on the assessment reports and opinions were presented for discussion.

Discussion took place on the appropriateness of the available CAS numbers to be used to describe PHMB (1600; 1.8). The CAS number 27083-27-8 was proposed by the Working Group APCP to be used for PHMB (1600; 1.8) although a second CAS number (32289-58-0) would also describe the substance. It was agreed to include both CAS numbers 32289-58-0 and 27083-27-8 for PHMB (1600; 1.8).

Further clarifications were requested on which information is necessary to characterise the impurities which were present in the test materials used for the eco-toxicological and toxicological studies. It was concluded that only justifications are necessary whether or not these impurities contribute to the eco-toxicological and toxicological properties, but no further testing on the individual impurities is requested.

In general, it was requested that the opinions shall always clearly state the uses evaluated, contain a conclusion in each section and have an overall conclusion and address the possibility for risk mitigation. COM asked to address why exposure leads to unacceptable risks in some PTs whereas for other PTs risks are acceptable for the environment. It was agreed that this would be reflected in the transmission letter of the opinions to the COM.

The following PT specific issues were discussed:

Product type 1:
The eCA explained that with respect to human health, a safe use was identified for professionals. For non-professional use a concern was identified for toddlers. Potential risk mitigation measures for toddlers were not assessed, since risks to the environment were unacceptable and could not be reduced. The eCA explained, with respect to environmental risks the market share was lowered and no further refinement was considered possible.

The non-approval opinion was adopted by consensus. One member noted that PHMB is used in soaps for the prevention of MRSA in hospitals. Member States may need to consider whether there is a need for PT 1 hand disinfectants using this active substance. However, for substances not meeting the exclusion criteria for which a non-approval decision is taken, derogations to non-approval based on essentiality is not foreseen in the BPR and is therefore not applicable.

Product type 2:
The CA guidance on *Authorisation of skin sensitiser biocidal products requiring PPE*[1] *for non-professional users* (CA-Sept13-Doc.6.2.a) considers a flexible approach and where justified allows products containing category 1B sensitisers to be authorised for non-professional users. In line with this guidance, the SECR asked if more explanation could be added on whether these conditions are fulfilled, in particular on the severity and frequency of contact during the pouring of the product into swimming pools. The eCA responded that no information is available on the frequency of contacts with PHMB during this use.However, the eCA considered the only difference with severe sensitizers between category 1A and 1B sensitisers is the dose where effects appear, but the severity of the effect is the same, ie sensitisation. The eCA referred to the safety phrases associated with the classification Cat 1B H317: P280 Wear protective gloves/protective clothing/eye protection/face protection. Some members supported the need for PPE, whereas others were argued for including the conclusions of the CA guidance to allow more flexibility at product authorisation when evaluating a consumer use. In any case, the use of the product by consumers would be restricted due to its classification as specific organ toxicity category 1. It was agreed to reflect in the opinion the flexible approach considered by the CA guidance.

A reverse reference scenario was used to address the potential risks arising from secondary exposure following dipping of medical equipment. The eCA argued that the cut-off value of rubbing 7 m^2 of disinfected medical equipment a day by a person is realistic and that the evaluation was sent to an ad-hoc follow-up where it was not challenged. The SECR stated that the outcome assumes a residue transfer from the treated surface to the palms of both hands over 170 times a day. The eCA considered that in hospitals, a person being in charge of pre-cleaning of equipment may spend all day manipulating equipment and therefore contact with 7 m^2 is not considered unrealistically high.

The risk identified to human health of the general public related to the secondary exposure from the application of ready to use (RTU) wipes is based on the infant crawling on treated surfaces and mouthing scenario. For the environment, the small scale surface treatment for RTU wipes relates to 10% of the large scale treated area (interim solution agreed at ENV WG III/2015). RTU on itself may be considered as small scale application. At product authorisation a new RTU scenario should be considered if available.

[1] personal protective equipment (PPE)

COM clarified that only general disinfectants can be authorised for PT 2 uses. If the disinfectant is specifically sold for the disinfection of specific medical devices, it is considered as an accessory to these medical devices and will not be in the scope of the BPR.

Product type 3:
The eCA has performed a livestock exposure assessment and a preliminary dietary risk assessment for uses for which no harmonised scenario is available. Noting that the assessment was based on maximalist assumptions, the eCA considered it as a crucial part of the assessment for PT 3. The eCA claimed that the conclusions give information on the risks of the substance that may be valuable for the European Medicines Agency (EMA) to start considering MRLs and gives an indication for the applicant that refinement and further information is needed at product authorisation. Several members supported the eCA in keeping the preliminary assessment and conclusion relating to the indirect exposure of consumers via food in the assessment. The SECR noted that the draft guidance on livestock exposure will only provide information on whether a Maximum Residue Limit (MRL) assessment is triggered. The draft guidance for livestock exposure does not provide a methodology to assess dietary exposure and thus no conclusion can be drawn on the consumer safety of the application. In the cases where the assessment shows a potential concern, a formal MRL evaluation is triggered and the responsibility for undertaking the evaluation falls to the European Medicines Agency (EMA). As the threshold value in the draft livestock exposure guidance is in the majority of cases exceeded the worst case consumer exposure may be derived according to the recently published EMA guidance and compared to the acceptable daily intake (ADI). The result of the assessment will indicate if an MRL evaluation is needed, however, is not sufficient to conclude on the risks to consumers. The SECR noted that neither the livestock exposure nor the dietary risk assessment was discussed at the working group. With respect to the assessed scenarios for dietary risk assessment, the eCA clarified that in the absence of information on areas to be cleaned the assessment focussed on the dipping of equipment and wiping of areas e.g. small breeding areas where exposure might take place. The refinement was not possible in the absence of details of the application of the product. The applicant explained that the applied uses envisaged were e.g. disinfection of surfaces in veterinary practice areas; the disinfection of equipment was not specified as it was assumed that an indication of general disinfection was sufficient for the evaluation. It was noted that there are ongoing discussions at CA level to distinguish PT 2 and PT 3 borderline uses. Though the intended use was not clear in the application, the use for PT 3 covers more small surfaces in farms and not veterinary areas.
With respect to the environmental risk assessment one member stated that the interim solution for RTU products, which is the only safe use, has been agreed for PT 2 and 4, but not for PT 3 (ENV WG III/2015). However, the BPC accepted the risk assessment performed by the eCA. For RTU products, a new scenario should be considered at product authorisation.

The possibility of more general provisions was discussed, not specifying the animal categories and/or land where manure is spread. It was noted that it is not possible to distinguish between manure spread on grassland or arable land as a RMM. For small scale disinfection, it was agreed not to restrict the use to specific surface areas but to have a general provision referring to "small scale disinfection" only.

Product type 4:
SECR emphasized the difference between triggering an MRL assessment and assessing consumer safety. An MRL evaluation does not mean there is a concern for consumers. For PT 4 the draft guidance under development relates to estimating residue transfer to food. The draft guidance may serve in the future as the basis for triggering MRL assessment. There is no guidance under development for estimating consumer safety following professional uses and no guidance is envisaged for dietary risk assessment to

be prepared by ARTFood as such an assessment is not within its scope. For PT 4, dietary risk assessment can be performed for non-professional (residential) uses, for which draft guidance has been developed. A member noted that it was agreed to keep calculations for information but not as a condition in the absence of harmonised guidance.
For the environment, the small scale surface treatment for RTU wipes relates to 10% of the large scale treated area (interim solution agreed at ENV WG III/2015). RTU on itself may be considered as small scale application. At product authorisation a new RTU scenario should be considered if available.

Product type 6 and 9: In the absence of comments, no PT significant discussion took place.

Product type 11: the disposal following drainage of cooling systems and potential release to the environment was discussed.

The Assessment Reports were agreed by the BPC, subject to the changes agreed during the meeting.

The BPC adopted by consensus its opinions on an application for the approval of the active substance for PT 2, 3, 4 and 11 and for the non-approval for PT 1, 6 and 9.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 30 July 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 9 July** and publish it on the ECHA website.

7.6 Draft BPC opinion on cybutryne for PT 21

The Chairman welcomed the applicant and their expert 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 rapporteur presented the revised assessment report and opinion on the active substance cybutryne notified for product-type 21 in the review programme. The active substance was already discussed at two Technical Meetings in 2011 and 2012 operating under the Biocidal Products Directive, and under the BPC-8 meeting and the Working Group - Environment meeting II in 2015.

In the draft opinion the rapporteur expressed their main concerns and reasons for the non-approval proposal: i) cybutryne is a persistent and toxic substance; ii) cybutryne is a priority substance under the Water Framework Directive; iii) the MAMPEC model is underestimating the actual concentrations based on monitoring data; iv) the concentrations from the monitoring data exceed the predicted no-effect concentrations (PNEC); and v) there is no mechanism to control higher volumes being placed on the market compared to the current one.

The rapporteur and the SECR informed the BPC members about the outcome of the Working Group – Environment discussions in relation to the market share value and the use of monitoring data. As there was no consensus in the WG on whether the default value for the market share of 90% could be reduced, this issue was discussed first. Some members were in favour of reducing it based on the information provided by the

applicant, whereas others were not. The overall conclusion was that the MAMPEC model calculations do underestimate the concentrations shown by the monitoring data. As a consequence the applicability of using MAMPEC for cybutryne was questioned. It was decided to apply MAMPEC using the default market share as a first tier approach. A lower market share can subsequently be considered. However, higher tier data are available (monitoring data on the environmental concentrations of cybutryne) based on which a conclusion can be drawn on the acceptability of the risks.

Some members stated that in open sea background stations or in the Baltic Sea concentrations in marine sediments are above acceptable levels. This means there is no "space" for additional input to these systems. The applicant argued that using the reduced market share value the MAMPEC model shows no unacceptable risks for the restricted use on commercial ocean going vessels. In addition, the applicant claimed that the monitoring data are outdated and they cannot be considered relevant compared to the restricted use on commercial ocean going vessels planned by the applicant. The applicant considered that the monitoring data before 2010 result from other uses, in addition to PT 21. Studies in the UK show that concentrations decreased after a restriction in 2005. This was contested by the rapporteur. Several members referred to the information in the assessment report and to more recent monitoring data (for example in the context of the Water Framework Directive) which are not included in the evaluation), which show unacceptable levels in shipping lanes of ocean going vessels. Following a comment from the applicant the feasibility of self regulation by economic operators was discussed for the use of cybutryne for the intended use. A member stated that the use supported is an important use representing almost half of the PT 21 market in some countries and that also other PT 21 active substances are intended to be used only for commercial ships. It cannot be guaranteed that an increase in demand will be self regulated by economic operators to avoid the occurrence of risks in the environment.

The applicant requested that there must be more transparency on when and under which conditions market share data can be submitted to refine the default value. In addition, it should be made clear which data can be used to refine the default value. The Chairman stated that the SECR is currently preparing guidance on this issue.

The Assessment Report was agreed by the BPC, subject to the changes agreed during the meeting.

With respect to the opinion the member from Denmark abstained. The BPC adopted by consensus its opinion on the non-approval of cybutryne in PT 21.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 30 July 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 9 July** and publish it on the ECHA website.

7.7 Draft BPC opinion on triclosan for PT 1

The Chairman welcomed the applicant and their expert 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 eCA indicated that the applicant had asked for the possibility to submit a new study referring to Article 90 of the Biocidal Products Regulation (BPR). This article however concerns situations where concern arises from BPR provisions that were not included in the Biocidal Products Directive. For triclosan this is not the case and therefore Article 90 is not applicable. The Commission confirmed this interpretation.

The applicant introduced the issues presented in a position paper submitted to the BPC and requested the opinion to be revoked. The eCA approach not to accept additional studies between the WG meeting and BPC meeting was supported and agreed. The outcome of the tonnage scenario in the environmental assessment was agreed to be removed from the opinion as it is not considered appropriate for this use. It was agreed to include in the opinion that, depending on the results of the REACH evaluation for triclosan, the active substance might fulfil the exclusion criteria as the metabolite methyl-triclosan might be vB and vP.

It will be clarified that the only possible risk mitigation measure would be to decrease the concentration of triclosan in the soap or to collect and dispose the wastewater as hazardous waste after use. A suggestion to decrease the concentration of triclosan in the soap was however not considered acceptable at a WG meeting based on limited efficacy. A collection and disposal of wastewater after hand washing by special professional health care personnel (e.g. surgical operations personnel in hospitals) is not normal practise. Therefore, based on the evaluated use, it was concluded that there are no realistic possibilities for risk mitigation measures.

Additional minor changes were agreed according to eCA proposals in the Open issues Table.

The Assessment Report was agreed by the BPC, subject to the changes agreed during the meeting.

The BPC adopted by consensus its opinion for the non-approval of triclosan in PT 1.

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 30 July 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 9 July** and publish it on the ECHA website.

7.8 Draft BPC opinion on cyromazine for PT 18

The Chairman welcomed the applicants and their expert for this item. The Chairman noted that one applicant objected to the presence of ASOs during the discussion. The session was therefore closed.

First of all the SECR stated that the environmental risk assessment incorporated in the assessment report contained some deficiencies and that the eCA had agreed to recalculate the values and share the results with the BPC ENV WG before proceeding with the opinion. The comments made on the assessment report and the opinion in relation to the environment, were therefore not discussed.

In relation to the comments made by the applicant Novartis Animal Health in relation to the completeness of the evaluation the eCA agreed to review the information provided from both applicants. A comment made by a member in relation to methods of analysis

was not considered for discussion as the point was never raised during the working group phase. Some members commented on the lack of consistency in the human health risk assessment when referring to some reference values. The eCA agreed to review and amend the assessment report.

One member commented on the PBT assessment. SECR clarified that any of the changes suggested by this member would not change the outcome of the assessment of the substitution criteria. The eCA agreed to incorporate the concerns by the member in relation to the sediment compartment.

There were some comments in relation to the calculated values for the main metabolite melamine in groundwater and the assessment performed by the eCA. The eCA stated that they had followed the principles stated in the relevant guidance and also SANCO guidelines. The SECR agreed to incorporate the aspect of the relevance of the metabolite in the e-consultation on the environmental risk assessment.

The rapporteur agreed to clearly state in the opinion which uses have been assessed and which not for both human health and environment.

Actions:

- **SECR:** to launch an e-consultation on the environmental risk assessment.
- **SECR**: To schedule the draft BPC opinion for adoption for **BPC-13**.

7.9 Outcome of the written procedure for C(M)IT/MIT for PT 13

The Chairman informed the participants on the outcome of the written procedure launched on 4 May 2015 (in accordance with Article 20 of the Rules of procedure of the BPC) to amend the opinion adopted at BPC-10 for C(M)IT/MIT for PT 13. It was mentioned that 19 members having the right to vote reacted to the written procedure, which therefore was valid. 19 members voted in favour of the amendment as proposed by the rapporteur. One member abided by the minority position already expressed at BPC-10.

Actions:

- **SECR**: to forward the adopted opinion to COM **by 9 July** and publish it and the minority opinion on the ECHA website.

8 Any other business

8.1 Article 75(1)(g) request on sulfuryl fluoride

The SECR introduced the request from the COM related to monitoring data provided in line with the decision taken at that time on the inclusion of sulfuryl fluoride in Annex I of the Biocidal Products Directive (BPD). COM indicated that the opinion should contain a recommendation whether immediate action would be needed in light of the monitoring data or that this can await the renewal process. The member from SE indicated that there are two elements: i) the scientific evaluation of the monitoring data related to the global warming potential; ii) the assessment of whether the contribution compared to other greenhouse gasses is still negligible as concluded under the BPR. The latter is maybe more a policy related issue, although the contribution can be calculated and presented. The Chairman concluded to await the evaluation including this calculation.

Actions:

- **Rapporteur:** provide the draft opinion **by 20 August 2015.**
- **SECR:** to schedule the draft BPC opinion for adoption for **BPC-12**.

8.2 ARTFood ad-hoc Working Group guidance on "Estimating dietary risk from transfer of biocidal active substances into foods – non-professional uses"

The Chairwoman of ARTFood updated the BPC members on the activities of the ad hoc WG.

The "Draft Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses" has been published on ARTFood webpage. The document is being made available as a "pilot project" in order to collect feedback and is open for commenting for a one year period. This will allow applicants and Member State Competent Authorities to gain experience with the approach proposed and to send their comments and feedback in light of their experience. After one year, the comments will be reviewed and a new draft of the guidance will go through the ECHA guidance consultation procedure. Then, the draft guidance will be finalised and published on the ECHA webpage.

Two other documents are in the pipeline. The "Guidance on estimating livestock exposure to active substance used in biocidal product" is in advance drafting status and it went already through a public consultation launched by the Commission. The "Guidance on estimating transfer of biocidal active substance into foods – professional exposure" is still under revision and once finalised by ARTFood, it will go through ECHA guidance procedure. The timelines for the publication of these two guidance documents are not clearly defined since there is a policy discussion ongoing on MRLs for biocides that could affect the finalisation of the documents.

Actions:

- **Members** and **Stakeholders:** to apply and send comments on the draft guidance on "Estimating dietary risk from transfer of biocidal active substances into foods – non-professional uses" via the ECHA website.

8.3 List of endpoints for imidacloprid

The Chairman introduced document BPC-11-2015-20. The Chairman and the member from Germany introduced the document. Several members supported the revised PNEC derived for imidacloprid. One member pointed to the difference between the values derived under the BPR and PPP. This can be explained however by the new, recent, data taken into account under the BPR and the fact that different methodologies are applied, for example different assessment factors. One member stated that downstream consequences of the revised PNEC for product authorisation need to be discussed: does the revised PNEC affect existing authorisations or at which point of time does the new value apply? In addition, the dissemination of the revised list of endpoints (LoEP) was discussed.

Actions:

- **Rapporteur:** to update the revised Assessment Report including the LoEP.
- **SECR:** to disseminate the updated AR on CIRCABC and on the ECHA website

- **SECR**: to consult with COM on the implication for product authorisation of the revised PNEC and consider how stakeholders can be informed of the revised AR
- **SECR**: to prepare a document for **BPC-12** on the process of dissemination of revised ARs when new data are submitted after active substance approval.

8.4 APCP Working Group guidance document on "'Specification', 'Reference specification', 'Source' and 'Reference source' - terminology used for processes under the Biocidal Products Regulation (BPR) (EU) No 528/2012"

Several members welcomed the document and agreed with the content. However, SECR was asked to clarify the guidance process with respect to the endorsement and entry into force and publication. For this the Chairman referred to agenda item 8.8. With respect to the guidance many members urged ECHA to apply flexibility, especially for the priority list 1 and 2 dossiers. The following argument were brought forward for this flexibility: i) the dossiers from the Review Programme were submitted in 2004 – 2008 when the data requirements were different: no 5 batch analysis was needed; ii) the aspect of reference specification did not receive much attention in the beginning of the implementation of the Review Programme; iii) limited levels of expertise in different MSCAs where many lack expertise in this specific field. Several members consequently requested SECR to apply flexibility and assist MSCAs and applicant, where possible. The SECR agreed to this and mentioned also that a harmonised template is developed to present the information in the CAR. SECR referred also to technical equivalence and chemical similarity: it is important for ECHA to have a clear description of the reference specification where the alternative source needs to be compared to.

The Chairman concluded that the meeting agreed with the document and the publication of it. With respect to the publication the Chairman indicated the intention is to incorporate the document in "Part A: Information Requirements". As this will take some time the intention is to publish the document under as transitional guidance on the ECHA web-site (http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation/transitional-guidance).

The Chairman concluded that the guidance will be applied by ECHA at accordance check stage from the next process flow.

Actions:

- **SECR:** to disseminate the document on the ECHA website.
- **SECR:** to apply the guidance at the accordance check.

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

The SECR introduced document on amending the working procedure for active substance approval. The document proposed different options which were opened for discussion. Several members supported moving the commenting round, (option 3) and were not in favour of reducing the time on steps before the Working Group (WG) meeting (option 2). The preparation of the WGs and the agreements taken there are key elements of the procedure. A member urged to implement option 3 as soon as possible and not wait for 2017. Other members were not in favour of option 3 either and requested for more

clarity on how the process would work, e.g. what issues are checked before and after accordance. A member commented that it would be more efficient to keep the deadlines as they are, however, if deadlines are not met to postpone the BPC discussion. The need to prevent discussions of immature dossiers at the BPC was stressed. The member also favoured option 2, extending the time between the WG and the BPC. In the view of this member option 3 may lead to difficult situations to manage as the responsibilities, in particular when there are major issues are not clear. COM expressed reservation to moving the commenting as the major issues in the active substance approval process will not be solved. The accordance check would be transformed from a light review to an active period of work with the commenting periods likely coinciding with the BPC. In addition, the overall workload may increase when managing 50 opinions and the dossiers under commenting. Moreover, it might happen that a dossier is commented but will be put on hold due to priority setting. COM took note of the intention that with the third option the 270 days of the peer review is exceeded. The SECR noted that the intention was to allow more time between the WG and the BPC, but adaptation will be inevitable to shorter time periods and higher turn-over of dossiers.

Actions:

- **Members:** to send comments to **SECR** by **17 July 2015.**
- **SECR:** to prepare a proposal on amending the working procedure with the aim of discussing the document at **BPC-12.**

8.6 PAR template for Union Authorisation

The PAR template for Union authorisation (UA) was presented for information.

The PAR template was revised according to the discussion in the Coordination Group (CG) Meeting in May 2015 on the PAR template for National authorisation. The PAR template for National authorisation (NA) was agreed by the CG and endorsed by the CA Meeting in May 2015. The PAR template for Union authorisation is adapted from the PAR template for National authorisation by incorporating the elements specific for the Union authorisation process.

Both the PAR template for NA and for UA will be made publicly available on the ECHA website. The templates can be used by the applicants and the Member State Competent Authorities when preparing their assessments.

Two members indicated that they would provide some minor comments to the template. One member suggested that the PAR template for Union authorisation should be used by the Competent Authorities immediately after publication.

Actions:

- **SECR:** to disseminate the PAR template on the ECHA website.
- **Members**: to send comments to the SECR **by 25 June 2015**.

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

One member indicated that there is a need for a harmonised approach on the possibility to introduce new information during the peer review process. Different situations have occurred so far where sometimes applicants were given the opportunity to submit new information at different stages of the process, even after the discussions in the Working Groups, but also this was refused by MSCAs. As this may lead to unequal treatment of applicant the member asked for guidance from the SECR or the Commission. The

Chairman indicated that the SECR is actually working on such a document as a follow-up from the workshop discussed under agenda item 8.5.

Actions:

- **SECR:** to prepare a proposal on introducing new information during the peer review process with the aim of discussing the document at **BPC-12.**

8.8 Applicability of guidance and guidelines

One member requested attention for guidance development with respect to the following issues: i) clarity on the complete procedure; ii) clarity on when to implement the guidance and who decides on this; iii) possibility for all MSCAs to be involved. This was supported by several other members. SECR indicated that such a document is under preparation and a draft version was presented for information at the last Working Groups. SECR clarified this was for information and not for agreement. The document was a thought-starter where the Working Group members were asked to comment before a final version is developed by the SECR for discussion at the BPC. In addition the document contains a proposal on how to simplify the exposure assessment procedure in the active substance approval process. The SECR referred to the mandate of the Working Groups with respect to guidance development. Several members argued for harmonisation and predictability of the process and referred for example to amended default values in a scenario which can have an impact on the outcome of the risk assessment. SECR stated that the most relevant seem to be indeed amendments of Emission Scenario Documents, scenarios or default values. This starts however often where a MSCA indicates something is incorrect in the current guidance or there is no guidance. One member confirmed this and argued that in the case of missing guidance where there is for example no (harmonised) scenario for a certain use, it is preferable to use a draft intermediate non-harmonised scenario. The Chairman concluded that the SECR will take this discussion into account when preparing the document and invited the BPC members to react on the thought-starter prepared by the SECR for the last Working Groups.

Actions:

- **SECR:** to prepare a proposal on the applicability of guidance in the peer review process and the procedure to be followed for the decision making process on when guidance should apply, with the aim of discussing the document at **BPC-12.**

8.9 Working procedure for active substance approval: timing and format for providing the draft final CA report and the open issues documents and ensuring the incorporation of agreed amendments in the final opinions

One member raised several issues with respect to the working procedure for active substance approval:

1. Reminding eCAs to submit the Draft Final CAR 26 days before the BPC meeting as there is only a limited time to comment on it, being 6 days, whereas it is difficult to discuss a draft assessment report and opinion without having been able to comment on the Draft Final CAR. In addition, the Draft Final CAR must be submitted in track-changes. The meeting agreed although it was stated by some members that the dead-lines are sometimes not compatible, especially in case of an ad-hoc follow-up after the Working Group.
2. Proposing to include the answers of the rapporteur in the open issue table distributed for the BPC meeting and have only one version, or at least keep the

original numbering. Some members supported this proposal although it may be difficult to manage in the current time line, being approximately one week. Chairman stated that a consolidated version including all comments is prepared and distributed by SECR as soon as possible, enabling members to look at all comments received. In addition, SECR aims to include the reactions from the rapporteur but considering the short timeline this is not always feasible.

3. Proposing to include an additional step in the procedure after adoption of the opinion in the BPC enabling members to check if agreements have all been incorporated in the final version which is distributed to the Commission. Some members supported this proposal, whereas another member stated this could be left to the rapporteur and the SECR. Chairman stated that often sections 2.3 – 2.5 are discussed at the BPC approving revised version after a first discussion.

The Chairman concluded: ad 1) the Draft Final CAR needs to be submitted in track changes; ii) considering the short time line of one week it will be very difficult to include the reactions from the eCA in the open issue table. The issue will be considered by SECR when preparing the proposal under agenda item 8.5.; iii) The issue will be considered by SECR when preparing the proposal under agenda item 8.5.

Actions:

- **SECR:** to consider consulting the BPC on the final opinions before submission to the COM

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 at the 11th meeting of BPC

15-18 June 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-10	
The revised version of the minutes of BPC-10 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. **SECR** to consider at the Environment Working Group the scenario for the use of disinfectants in PT 3 in footbaths.
Item 6 - Work programme for BPC	
6.1 Revised Work Programme 2015-2016	
	Members: to send information on any further changes to the Work Programme (WP) to the SECR **by 26 June 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	
Priority shall be given to the first and second priority list substances of the Review Programme Regulation.	**Members**: to check the information in the tables for their active substance/PT combinations and inform the SECR of any corrections **by 31 July 2015**. **SECR:** to include the information provided, schedule the substance/PT combinations in the Work Programme and present an update of the outlook at BPC-12.
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	
With respect to the opinions it was re-iterated that the following aspects shall be clearly	**Members:** to apply the standard phrases in future

described: i) which uses were assessed?; ii) the risks identified for human health and environment; iii) overall conclusion on the safe uses identified; iv) discussion and proposal for risk mitigation measures. Several recommendations were made to improve the opinions template in this respect which will be considerd by the **SECR**.	draft opinions. **SECR:** to revise and upload the Assessment Report and opinion templates to the BPC CIRCABC IG after the meeting.
7.2 Draft BPC opinion on biphenyl-2-ol for PT 3, 4 and 6	
The BPC adopted by consensus its opinions on an application for the approval of the active substance for PT 4 and 6. It was agreed to launch an e-consultation on the environmental risk assessment for PT 3.	**For PT 4 and 6:** **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 30 July 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 opinion to COM **by 9 July 2015** and publish it on the ECHA website. **For PT 3:** **SECR:** to launch an e-consultation on the environmental risk assessment. **SECR**: To schedule the draft BPC opinion on biphenyl-2-ol adoption for **BPC-13**.
7.3 Confirmation of the conclusions of the combined CAR for DDAC for PT 8	
The BPC confirmed the conclusions of the combined assessment report for DDAC.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 30 July 2015.** **SECR:** to disseminate the combined assessment report on CICRCA BC and on the ECHA website.
7.4 Confirmation of the conclusions of the combined CAR for ADBAC/BKC for PT 8	
The BPC confirmed the conclusions of the combined assessment report for ADBAC/BKC.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 30 July 2015.** **SECR:** to disseminate the combined assessment report on CIRCA BC and on the ECHA website.
7.5 Draft BPC opinion on PHMB for PT 1, 2, 3, 4, 6, 9 and 11	
The BPC adopted by consensus its opinions on an application for the approval of the active substance for PT 2, 3, 4 and 11. The BPC adopted by consensus its opinions on the non-approval for PT 1, 6 and 9. The substance is considered a candidate for substitution in accordance with Article 10(1)(d).	**Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 30 July 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 9 July** and publish it on the ECHA website.

7.6 Draft BPC opinion on cybutryne for PT 21	
The BPC adopted by consensus its opinion for the non-approval of this active substance/PT combination. The substance is considered a candidate for substitution in accordance with Article 10(1)(d) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 30 July 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 9 July** and publish it on the ECHA website.
7.7 Draft BPC opinion on triclosan for PT 1	
The BPC adopted by consensus its opinion for the non-approval of this active substance/PT combination. The substance is considered a candidate for substitution in accordance with Article 10(1)(d) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 30 July 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 9 July** and publish it on the ECHA website.
7.8 Draft BPC opinion on cyromazine for PT 18	
It was agreed to launch an e-consultation on the environmental risk assessment.	**SECR:** to launch an e-consultation on the environmental risk assessment. **SECR**: To schedule the draft BPC opinion for adoption for **BPC-13**.
7.9 Outcome of the written procedure for C(M)IT/MIT for PT 13	
The SECR informed the BPC on the outcome of the written procedure to amend the opinion adopted at BPC-10 for C(M)IT/MIT for PT 13. The BPC adopted the amended opinion by consensus *via* the written procedure.	**SECR:** to forward the adopted opinion to COM **by 9 July** and publish it on the ECHA website.
Item 8 – Any other business	
8.1 Article 75(1)(g) request on sulfuryl fluoride	
The BPC agreed to • The BPC member from Sweden to act as Rapporteur for the Article 75(1)(g) request • to the scope of the request • no BPC WG discussion is necessary • the timelines proposed.	**Rapporteur:** provide the draft opinion **by 20 August 2015.** **SECR:** to schedule the draft BPC opinion for adoption for **BPC-12**.
8.2 ARTFood ad-hoc Working Group guidance on "Estimating dietary risk from transfer of biocidal active substances into foods – non-professional uses"	
The SECR informed the BPC on the status of the draft guidance under development by ARTFood. The draft guidance on "Estimating dietary risk from transfer of biocidal active substances into foods – non-professional uses" is uploaded to	**Members** and **Stakeholders:** to apply and send comments on the draft guidance on "Estimating dietary risk from transfer of biocidal active substances into foods – non-professional uses" via the ECHA website.

ECHA website as a pilot project for testing the guidance.	
8.3 List of endpoints for imidacloprid	
The BPC agreed to the amendment of the PNEC value as derived by the Environmental Working Group.	**Rapporteur:** to update the revised Assessment Report including the LoEP. **SECR:** • to disseminate the updated AR on CIRCABC and on the ECHA website. • to consult with COM on the implication for product authorisation of the revised PNEC and consider how stakeholders can be informed of the revised AR. • to prepare a document for **BPC-12** on the process of dissemination of revised ARs when new data are submitted after active substance approval.
8.4 APCP Working Group guidance document on "'Specification', 'Reference specification', 'Source' and 'Reference source' - terminology used for processes under the Biocidal Products Regulation (BPR) (EU) No 528/2012"	
The BPC agreed to the guidance document and to the proposal from ECHA to apply it at the accordance check. The BPC requested that flexibility should be applied, for example with respect to the information required, in line with the timing of the submissions under the Review Programme.	**SECR:** to disseminate the document on the ECHA website. **SECR:** to apply the guidance at the accordance check.
8.5 Follow-up on the Workshop "Reviewing the active substance assessment process"	
	Members: to send comments to **SECR** by **17 July 2015.** **SECR:** to prepare a proposal on amending the working procedure with the aim of discussing the document at **BPC-12.**
8.6 PAR template for Union Authorisation	
	SECR: to disseminate the PAR template on the ECHA website. **Members**: to send comments to the SECR **by 25 June 2015**.
8.7 Possibility of introducing new data or new information during the peer review process	
	SECR: to prepare a proposal on introducing new information during the peer review process with the aim of discussing the document at **BPC-12.**
8.8 Applicability of guidance	
	SECR: to prepare a proposal on the applicability of guidance in the peer review process and the procedure to be followed for the decision making process on when guidance should apply, with the

	aim of discussing the document at **BPC-12.**
8.9 Working procedure for active substance approval	
Members were reminded of keeping the deadlines for the submission of the revised CAR (DocII). Rapporteurs were encouraged to submit their responses to the comments on the draft opinions.	**SECR:** to consider consulting the BPC on the final opinions before submission to the COM.

Part III - List of Attendees

Members	European Commission
BORGES Teresa (PT)	CHATELIN Ludovic (DG SANTE)
BROVKINA Julija (LV)	
ČEBAŠEK Petra (SI)	**Advisers**
CHEZEAU Aurélie (FR)	CRESTI Raffaella (IT)
CHROBAK Robert (PL)	GONZÁLEZ GONZÁLEZ Lorena (ES)
COSTIGAN Michael (UK)	KOMEN Corine (NL)
DONS Christian (NO)	PALOMÄKI Jaana (FI)
DRAGOIU Mihaela-Simona (RO)	PLATTNER Edmund (AT)
GONZALEZ MARQUEZ Luisa (ES)	RAMOS SCHEGEL Carmen (ES)
HAHLBECK Edda (SE)	SCHMIDT Marianne (DK)
JÄGER Stefanie (DE)	THIERRY-MIEG Morgane (FR)
MERISTE Anu (EE) *(attending on 17-18 June)*	VAN GALEN Joost (NL)
LARSEN Jørgen (DK)	WEINHEIMER Viola (DE)
NELEMANS Maartje (NL)	
RUBBIANI Maristella (IT)	**Accredited Stakeholder Organisations**
SPATNY Nina (AT)	BRUYNDONCKX Raf (Cefic)
TUUSA Tiina (FI)	
VACEK Tomáš (CZ)	**ECHA Staff**
VAN BERLO Boris (BE)	GUTIERREZ ALONSO Simon
VRHOVAC FILIPOVIC Ivana (HR)	JANOSSY Judit
ZOUNOS Athanasios (EL)	KREBS Bernhard
	NEGULICI Ligia
Alternate members	RUGGERI Laura
GAVRIEL Alexandros (CY)	VAN DE PLASSCHE Erik
KULD Piret (EE) *(attending on 15-16 June)*	
PYTHON François (CH)	
WHELAN Michelle (IE)	
Invited expert	
SZÁNTÓ Emese (HU)	

Applicants	Apologies
CHAMP Samantha (BASF) for cybutryne PT 21 and triclosan PT 1	BUSUTTIL Ingrid (MT)
DEN HARTOG Ilona (Akzo Nobel) for DDAC PT 8 and ADBAC/BKC PT 8	CAZELLE Elodie (AISE)
DIN Salahud (Lonza) for PHMB PT 1, 2, 3, 4, 6, 9 and 11	MAJUS Saulius (LT)
DORNIEDEN Hiltrud (Novartis Animal Health) for cyromazine PT 18	MIKOLASKOVA Denisa (SK)
FREEMANTLE Mike (Lonza) for DDAC PT 8 and ADBAC/BKC PT 8	REID Kirsty (Eurogroup for Animals)
MUNK Wolfgang (Hokochemie) for cyromazine PT 18	ZIGRAND Jeff (LU)
STROECH Klaus (Lanxess) for biphenyl-2-ol PT 3, 4 and 6	
Experts accompanying applicants	
FREEMANTLE Mike, accompanying DIN Salahud, for PHMB PT 1, 2, 3, 4, 6, 9 and 11	
MILLER Natalie, accompanying DORNIEDEN Hiltrud, for cyromazine PT 18	
MITSIKOSTA Foteini, accompanying STROECH Klaus, for biphenyl-2-ol PT 3, 4 and 6	
PAWLOWSKI Sascha, accompanying CHAMP Samantha, for cybutryne PT 21	
PETER Sven, accompanying CHAMP Samantha, for triclosan PT 1	

Part IV - List of Annexes

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

Annex II Final agenda of BPC-11

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-11 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2	BPC-A-11-2015_rev3	Draft final agenda	
4	BPC-M-10-2015_rev1	Draft minutes from BPC-10	
5.2	BPC-11-2015-01	Admin issues and report from the other Committees	
6.1	BPC-11-2015-02	BPC updated Work Programme 2015-2016	
6.2	BPC-11-2015-03	Outlook	
7.1	BPC-11-2015-04	Catalogue of specific conditions and elements at the PA stage	
7.9	BPC-11-2015-25	Outcome of the written procedure for C(M)IT/MIT for PT 13	
8.1	BPC-11-2015-19	Article 75(1)(g) request on sulfuryl fluoride	
8.3	BPC-11-2015-20	List of endpoints for imidacloprid	
8.4	BPC-11-2015-21	APCP Working Group guidance document on "'Specification', 'Reference specification', 'Source' and 'Reference source' "	
8.5	BPC-11-2015-23	Follow-up on the Workshop "Reviewing the active substance assessment process"	
	BPC-11-2015-23A	Comments from Austria on doc BPC-11-2015-23	
8.6	BPC-11-2015-24A	PAR template for Union Authorisation – track changes template	
	BPC-11-2015-24B	PAR template for Union Authorisation – clean template	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.2	BPC-11-2015-05A	Biphenyl-2-ol PT 3	Draft opinion
	BPC-11-2015-05B		Assessment report
	BPC-11-2015-05C		Open issues
7.2	BPC-11-2015-06A	Biphenyl-2-ol PT 4	Draft opinion
	BPC-11-2015-06B		Assessment report
	BPC-11-2015-05C		Open issues

7.2	BPC-11-2015-07A	Biphenyl-2-ol PT 6	Draft opinion
	BPC-11-2015-07B		Assessment report
	BPC-11-2015-05C		Open issues
7.3	BPC-11-2015-08A	DDAC PT 8	Cover note
	BPC-11-2015-08B		Combined CAR
	BPC-11-2015-08C		Open issues
7.4	BPC-11-2015-08A	ADBAC/BKC PT 8	Cover note
	BPC-11-2015-09		Combined CAR
	BPC-11-2015-09A		Open issues
7.5	BPC-11-2015-10A	PHMB PT 1	Draft opinion
	BPC-11-2015-10B		Assessment report
	BPC-11-2015-10C		Open issues
7.5	BPC-11-2015-11A	PHMB PT 2	Draft opinion
	BPC-11-2015-11B		Assessment report
	BPC-11-2015-10C		Open issues
7.5	BPC-11-2015-12A	PHMB PT 3	Draft opinion
	BPC-11-2015-12B		Assessment report
	BPC-11-2015-10C		Open issues
7.5	BPC-11-2015-13A	PHMB PT 4	Draft opinion
	BPC-11-2015-13B		Assessment report
	BPC-11-2015-10C		Open issues
7.5	BPC-11-2015-14A	PHMB PT 6	Draft opinion
	BPC-11-2015-14B		Assessment report
	BPC-11-2015-10C		Open issues
7.5	BPC-11-2015-15A	PHMB PT 9	Draft opinion
	BPC-11-2015-15B		Assessment report
	BPC-11-2015-10C		Open issues
7.5	BPC-11-2015-16A	PHMB PT 11	Draft opinion
	BPC-11-2015-16B		Assessment report
	BPC-11-2015-10C		Open issues
7.6	BPC-11-2015-17A	Cybutryne PT 21	Draft opinion (non-approval)
	BPC-11-2015-17A(2)		Draft opinion (approval)
	BPC-11-2015-17B		Assessment report
	BPC-11-2015-17C		Open issues
	BPC-11-2015-17D		eCA position paper
7.7	BPC-11-2015-18A	Triclosan PT 1	Draft opinion
	BPC-11-2015-18B		Assessment report
	BPC-11-2015-18C		Open issues

	BPC-11-2015-18D		Comments on draft CAR and eCA response
	BPC-11-2015-18E		Comments on draft CAR and eCA response_2
7.8	BPC-11-2015-22A	Cyromazine PT 18	Draft opinion
	BPC-11-2015-22B		Assessment report
	BPC-11-2015-22C		Open issues

11 June 2015
BPC-A-11-2015_rev3

Revised draft agenda

11th meeting of the Biocidal Products Committee (BPC)

15-18 June 2015

ECHA Conference Centre, Annankatu 18, Helsinki

15 June: starts at 13:30
18 June: ends at 13:00

Item 1 – Welcome and apologies

Item 2 – Agreement of the agenda

BPC-A-11-2015_rev3

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-10

BPC-M-10-2015_rev1

For agreement

Item 5 – Administrative issues

5.1 Housekeeping issues

For information

5.2 Other administrative issues and report from other Committees

BPC-11-2015-01

For information

Item 6 – Work programme for BPC

6.1 Revised BPC Work Programme 2015-2016

BPC-11-2015-02

For information

6.2 Outlook

BPC-11-2015-03

For discussion

Item 7 – Applications for approval of active substances[2]

7.1 Working procedure and templates: update from SECR

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

BPC-11-2015-04

For information

7.2 Draft BPC opinion on biphenyl-2-ol for PT 3, 4 and 6

Previous discussion(s): WG-V-2014 and BPC-9

PT 3: BPC-11-2015-05A, B and C

PT 4: BPC-11-2015-06A and B; BPC-11-2015-05C

PT 6: BPC-11-2015-07A and B; BPC-11-2015-05C

For adoption

7.3 Confirmation of the conclusions of the combined CAR for DDAC for PT 8

Previous discussion(s): TM-III-2008, TM-IV-2008, TM-I-2009, TM-II-2009, TM-II-2013 and WG-II-2015

BPC-11-2015-08A, B and C

For agreement

7.4 Confirmation of the conclusions of the combined CAR for ADBAC/BKC for PT 8

Previous discussion(s): TM-III-2008, TM-IV-2008, TM-I-2009, TM-II-2009 and TM-II-2013

BPC-11-2015-08A, BPC-11-2015-09 and BPC-11-2015-09A

For agreement

7.5 Draft BPC opinion on PHMB for PT 1, 2, 3, 4, 6, 9 and 11

Previous discussion(s): WG-III-2014 and WG-I-2015

PT 1: BPC-11-2015-10A, B and C

PT 2: BPC-11-2015-11A and B; BPC-11-2015-10C

PT 3: BPC-11-2015-12A and B; BPC-11-2015-10C

PT 4: BPC-11-2015-13A and B; BPC-11-2015-10C

PT 6: BPC-11-2015-14A and B; BPC-11-2015-10C

PT 9: BPC-11-2015-15A and B; BPC-11-2015-10C

PT 11: BPC-11-2015-16A and B; BPC-11-2015-10C

For adoption

7.6 Draft BPC opinion on cybutryne for PT 21

Previous discussion(s): TM-III-2011, TM-I-2012, BPC-8 and WG-II-2015

[2] 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).

BPC-11-2015-17A, A(2), B, C and D

For adoption

7.7 Draft BPC opinion on triclosan for PT 1

Previous discussion(s): WG-V-2014

BPC-11-2015-18A, B, C, D and E

For adoption

7.8 Draft BPC opinion on cyromazine for PT 18

Previous discussion(s): TM-II-2012, WG-I-2015

BPC-11-2015-22A, B and C

For adoption

7.9 Outcome of the written procedure for C(M)IT/MIT for PT 13

BPC-11-2105-25

For information

Item 8 – Any other business

8.1 Article 75(1)(g) request on sulfuryl fluoride

BPC-11-2015-19

For agreement

8.2 ARTFood ad-hoc Working Group guidance on "Estimating dietary risk from transfer of biocidal active substances into foods – non-professional uses"

For information

8.3 List of endpoints for imidacloprid

BPC-11-2105-20

For discussion

8.4 APCP Working Group guidance document on "'Specification', 'Reference specification', 'Source' and 'Reference source' - terminology used for processes under the Biocidal Products Regulation (BPR) (EU) No 528/2012"

BPC-11-2015-21

For information

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

BPC-11-2015-23, BPC-11-2015-23A

For discussion

8.6 PAR template for Union Authorisation

BPC-11-2015-24A and B

For information

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

(item added during the meeting)

For discussion

8.8 Applicability of guidance and guidelines

(item added during the meeting)

For discussion

8.9 Working procedure for active substance approval

- Timing and format for providing the draft final CA report and the open issues documents
- Ensuring the incorporation of agreed amendments in the final opinions

(item added during the meeting)

For discussion

Item 9 – Agreement of the action points and conclusions

For agreement

Provisional timeline for the

11th meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Annankatu 18, Helsinki

15 June 2015: starts at 13:30
18 June 2015: ends at 13:00

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

Monday 15 June: afternoon session

Items 1-5	Opening items and administrative issues
Item 6	Work programme of the BPC 2015-16
Item 7	Applications for approval of active substances
Item 7.1	Working procedures and templates
Item 7.2	Draft BPC opinion on biphenyl-2-ol for PT 3, 4, 6
Item 7.3	Confirmation of the conclusions of the combined CAR for DDAC PT 8
Item 7.4	Confirmation of the conclusions of the combined CAR for ADBAC/BKC for PT8

Tuesday 16 June: morning session

Item 7	Follow up to previous discussions on draft substance opinions
Item 7.5	Draft BPC opinion on PHMB for PT 1, 2, 3, 4, 6, 9, 11

Tuesday 16 June: afternoon session

Item 7.5(cont'd)	Draft BPC opinion on PHMB for PT 1, 2, 3, 4, 6, 9, 11

Wednesday 17 June: morning session

Item 7.	Follow up to previous discussions on draft substance opinions
Item 7.6	Draft BPC opinion on cybutryne for PT 21

Wednesday 17 June: afternoon session

Item 7.7	Draft BPC opinion on triclosan for PT 1
Item 7.8	Draft BPC opinion on cyromazine for PT 18
Item 7.9	Outcome of the written procedure for C(M)IT/MIT for PT 13

Thursday 18 June: morning session

Item 7	Follow up to previous discussions on draft substance opinions
Item 8	Any other business
Item 8.1	Article 75(1)(g) request on sulfuryl fluoride
Item 8.2	ARTFood ad-hoc Working Group guidance on "Estimating dietary risk from transfer of biocidal active substances into foods – non-professional uses"
Item 8.3	List of endpoints for imidacloprid
Item 8.4	APCP Working Group guidance document on '"Specification', 'Reference specification', 'Source' and 'Reference source' - terminology used for processes under the Biocidal Products Regulation (BPR) (EU) No 528/2012"
Item 8.5	Follow-up on the Workshop "Reviewing the active substance assessment process"
Item 8.6	PAR template for Union Authorisation
Item 8.7	Possibility of introducing new data or new information during the peer review process

Item 8.8	Applicability of guidance and guidelines
Item 8.9	Working procedure for active substance approval • Timing and format for providing the draft final CA report and the open issues documents • Ensuring the incorporation of agreed amendments in the final opinions
Item 9	Agreement of the action points and conclusions