12 December 2014

BPC-M-7-2014

Final minutes of the 7th meeting of the Biocidal Products Committee (BPC)

30 September – 3 October 2014

Part I - Summary Record of the Proceedings

1. Welcome and apologies

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

The Chair introduced Ligia Negulici, the new administrative assistant in the BPC Secretariat.

The Chair welcomed the recently appointed new member from the Czech Republic, Tomas Vacek, along with his alternate member, Jan Mikolas and from the Slovak Republic, the member Denisa Mikolaskova, and the alternate member, Jana Chmelikova,.

The Chair also introduced the new observer from AISE, Elodie Cazelle, who has replaced Gosia Oledzka who has now left AISE. The Chair thanked Gosia for her contribution to the BPC during the set-up phase.

The Chair explained that during the meeting two colleagues from the Executive Office would be present in the context of an ongoing ECHA project to look for ways of increasing efficiency and to ready ECHA for the upcoming ISO 9001 certification process.

The Chair informed BPC members of the participation of 25 members including four alternates, 14 advisers, two representatives of the European Commission and three representatives from accredited stakeholder organisations (ASOs). Apologies were received from three members and one from the ECHA accredited stakeholder organisation (ASO) representing the three animal welfare organisations.

Applicants were also 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

A revision of the agenda was tabled as a room document, however a further change had been necessary so the Chair introduced a revision two version of the final draft agenda (BPC-A-7-2014 rev 2) and invited any additional items. The agenda was agreed without any further changes. The list of meeting documents and the final version of the agenda are included in Part IV.

The Chair also 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.

One additional meeting document was tabled as room document: SE position on MIT (BPC-7-2014-12E).

Actions:

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

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 the status of the actions arising from BPC-6

The Chair noted that a number of comments had been received on the draft minutes and reminded members to restrict their proposals for amendments on the minutes to those aspects where their position has been reported or where an amendment is necessary for clarification. The revised draft minutes from BPC-6 (BPC-M-6-2014_rev 1) were agreed taking into account the proposed changes by the Commission and from several members. The agreed minutes were to be uploaded to the BPC CIRCABC IG and to the ECHA website after the meeting.

The Chair updated members on the status of the actions arising from BPC-6 and noted most items had been completed, but updated members on on-going items. In relation to action item 4, on the PBT assessment of metabolites and impurities, one member enquired whether this would include isomers? The Chair thanked the member for the intervention and agreed to include this aspect in a revised version of the paper for the next Biocides CA meeting.

The Secretariat (SECR) reported back on action item 11.1, Webex and remote connections. It was noted that the use of remote connections had been successfully piloted at the recent set of BPC Working Group (BPC WG) meetings, WG IV. As a result the use of remote connections will remain a possibility for future BPC WG meetings, although security rules mean discussions can usually only contain non confidential material so remote meetings or connections may not always be possible. As a corollary, in future if there are remote participants these will not be permitted to participate in closed sessions.

In relation to action item 9.1 concerning the work on disinfection by-products, the Chair invited the Dutch member to update the BPC on developments. The Dutch member explained that several volunteers from the Member State Competent Authorities (MSCAs) had come forward to assist in this work and a mandate for the task is being prepared. First discussions are expected later this year. In order to continue progressing the assessment reports for the dossiers which are currently on hold, it was decided to not await the development and adoption of the formal guidance on how to evaluate the possible formation of halogenated disinfection by-products.

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

In an attempt to improve the transparency of the documents, the SECR noted that at this meeting the substance documents had been numbered for the first time. For each substance the opinion is denoted by 'A' and then other substance documents are B, C, D etc. In addition, as requested at the last meeting, the open issue documents were to be uploaded to the BPC CIRCABC IG to include the outcome of the discussions after the meeting. Several members sought clarification on specific aspects of document naming and numbering, most of which were solved in the margins of the meeting. However, it was noted that sometimes the document names do not closely correspond to the title of the documents. It was agreed to tighten up this aspect.

In addition, the SECR explained the following:

- **Meeting length and date of registration** – as requested at BPC-6, the SECR will inform members well in advance of the proposed meeting length for the forthcoming meeting and when participants will be required to register for the meeting. The SECR invited members to ensure they register for the meeting as soon as possible to ensure ECHA can provide the most economically efficient travel;

- **BPC-8 and 9 planning** – the SECR drew to the attention of members that BPC-8 is scheduled for 2-5 December and BPC-9 is for 2-6 February 2015. The consequence of this is that there will be a relatively short time (by 19 December) after BPC-8 to finalise the adopted opinions, draft minutes and issue the invitations for BPC-9. Members are in particular therefore invited to assist in finalising the draft opinions as quickly as possible;

- **Advisers** – the SECR had taken a flexible approach when considering the various requests from members to have advisers for the purposes of accessing the BPC CIRCA BC Interest Group in order to facilitate the work of the MSCAs. Accordingly, a number of advisers had been granted access to CIRCABC. Nevertheless the SECR reminded members that they have a duty under the Biocidal Products Regulation (BPR) to ensure there is a coordination between the work of the Agency and the MSCAs;

- **Update to the assessment report templates** – the SECR noted updated templates had been made available over the summer in the BPC CIRCA BC IG to harmonise with the list of endpoints in the Competent Authority Report (CAR) template;

- **Revised BPC WG mandates** the permanent WG mandates had been slightly revised since the last meeting to make reference to the ECHA policy on conflicts of interest and the mandates for the Ad hoc WG on Human Exposure and ARTFood have been slightly revised to align the output of the BPC WGs with the ECHA guidance procedure;

- **Survey of members** – the SECR reported that BPC members and ASOs will be invited to respond to several questions in this year's annual survey of stakeholders that is to take place in November. A full survey will take place next year.

Actions:

- The SECR to ensure documents in CIRCABC have titles that correspond to the document name;
- To upload the final version of the open issue documents (with outcomes of the discussions included) to the BPC CIRCABC after the meeting, following an editorial check by the SECR.

6. Work Programme for BPC for 2014 – 15

The Chair introduced the BPC Work Programme (WP) for 2014 – 2015 (BPC-7-2014-17), asking members to inform the SECR of any changes. The Chair informed the BPC that due to the relatively high number of active substance/PT combinations scheduled for BPC-9, peracetic acid or hydrogen peroxide/PT combinations will be moved to the

following meeting. Bilateral discussions with the eCA (evaluating Competent Authority) will follow to decide which dossier will be moved.

The Chair informed the BPC that dossiers for MBO and HPT (formaldehyde releasers potentially meeting the exclusion criteria and submitted after 1 September 2013) will be put on hold until the RAC opinion is adopted.

The Chair communicated that the next meeting (BPC-8) will contain a special case (PBO), for which the BPC will need to consider whether it is an active substance or a synergist.

Members were informed that an overview of substances of the first priority list will be prepared for the next meeting. It concerns PTs 8, 14, 16, 18, 19, 21 for which the CAR needs to be submitted to ECHA by the end of 2015. Members were invited to inform the SECR of any change via the functional mailbox.

A member raised the issue of timing of Biocide CA and BPC meetings and noted that the short time between the two brings a heavy workload for members and may hinder efficiency. The Chair assured the issue will be looked into to the extent possible, considering also the fixed timelines between BPC and BPC WG meetings and other logistic issues.

Another member requested information on the possible timing of the RAC opinion for the two substances mentioned above, for which the dossiers will be put on hold. The Chair stated that the accordance check was completed for the two substances and that priority is given to these dossiers in the RAC process. He also mentioned that ECHA is in the process of developing an information system which is expected to be made available on the website and which will allow a check to made on the status of a certain substance in the various ECHA processes. It was agreed to consider updating the CLH/PBT overview table with RAC planning information, where available.

Actions:

The SECR to consider updating the CLH/PBT overview table with RAC planning information, where available;

- Members to send information on any changes to the Work Programme (WP) to the SECR;
- SECR to update the WP in the light of the information from members and upload the revised document to the BPC CIRCABC and the ECHA web site after the meeting. The WP is to be updated after each meeting, where appropriate;
- SECR and COM to consider reviewing the timing of CA and BPC meetings in 2015.

7. Applications for approval of active substances

7.1 Working procedure and templates: update from SECR

7.1a New data generated after AS approval

One member stated that, contrary to what is stated in the document in the second comment, the case described concerns new data from scientific literature not submitted by the applicant but incorporated by the MSCA. This new case will be added to the document.

One member stated that technical equivalence is a pre-condition for accepting data from third party dossiers or data originally included under Article 95 and subsequently submitted under product authorisation. This will be included in the document.

It was recognised that there are several cases as described in the document where additional data will become available after the approval of the active substance. In such cases the LoEP may need to be revised where several members argued that on the one hand the LoEP should not be updated 'too frequently', while on the other hand if the additional data have a significant impact on the outcome of the evaluation (for example leading to changes in threshold values) there is a need for a formal mechanism to endorse the evaluation of the additional data. The latter is especially relevant if existing authorisations need to be modified or cancelled. This will not so much occur for additional data for case 3 in section 2 of the document, but more when additional data are submitted for an endpoint for which data were already available (e.g. for third party dossiers or alternative supplier submissions under Article 95). In addition, it was stated by several members that a mechanism is needed on how to process the additional data to avoid double work as the data may be submitted to several MSCAs at the same time. The SECR proposed that the first MSCA receiving the additional data via an application for product authorisation informs the other MSCAs that the data were received and subsequently of its evaluation. COM asked about the evaluation of ECHA for submissions under Article 95 and how this can be made available to MSCAs in case the same data are submitted during product authorisation.

Furthermore it was discussed when and how to evaluate additional data for a third party dossier or an alternative supplier submission under Article 95 when a complete data set is provided. One member argued that only the more critical data have to be taken into account in the evaluation. The SECR proposed that the outcome of technical equivalence shall be considered here: if the technical equivalence is based on a tier 2 assessment there is no need to consider the data as there is no difference in toxicity with the reference source. Only if the technical equivalence is based on a tier 1 assessment the data may need to be considered.

Following a question from one member the SECR confirmed that in the current Product Assessment Report (PAR) template additional data for the active substance can be reported.

Actions:

- **Members:** to provide comments in writing by 24 October in the dedicated CIRCABC newsgroup;
- **SECR:** to prepare a revised document for the next meeting which includes a clarification for which cases and how data from third party dossiers will be incorporated in the LoEPs.

7.1b Standard phrases for active substance approval

The Chair introduced the revised version of the document, which has been distributed to the members via the BPC CIRCABC IG. In addition to standard phrases for conditions used in active substance approval, the catalogue now also contained elements to be taken into account when authorising products.

The Chair informed participants that the document will be updated for each meeting and presented for information during the meetings.

In relation to specific conditions for all product-types, fourth specific condition, one member questioned the wording 'when the active substance is a candidate for substitution' and asked whether the wording should be modified to include also those substances for which it is not yet certain if they are candidate for substitution.

The Chair clarified that the specific condition will be used only for the certain cases and added that for the cases in doubt this may be reflected in the opinion but not in the specific conditions.

One member referred to previous discussions at the Biocides CA meeting concerning the possibility of conducting comparative assessment at the product authorisation

stage for those substances which at a later stage meet the criteria, despite not being flagged as candidate for substitution at active substance approval. COM clarified that indeed in these cases a comparative assessment will have to be conducted at the product authorisation stage, but that it is not yet decided if the approval will be reviewed.

Following the comment of one member, the Chair agreed that the document should also address the case of active substances meeting the exclusion criteria for which the CAR was submitted before 1 September 2013.

In relation to specific conditions for all product-types, second specific condition one member suggested the use of the wording 'protective measures' instead of 'personal protective equipment (PPE)'. This was agreed..

The case of substances which meet two of the three PBT criteria and for which the recommendation of the PBT Expert Group (EG) was not yet submitted was also discussed, in particular whether such cases are to be considered as candidates for substitution or not. The Chair clarified that for dossiers submitted before 1 September 2013, ECHA relies on the evaluation of the eCA to start a public consultation (if the eCA assesses that the substance meets two of the three PBT criteria). For the dossiers submitted after 1 September 2013, the outcome of the PBT EGis needed.

Actions:

- Members: to apply the standard phrases in future draft opinions.
- SECR to upload the catalogue to the BPC CIRCA BC IG after the meeting and update after each meeting, where appropriate.

7.2 Draft BPC opinion on triflumuron for PT 18

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 Chair informed members that as no safe use for this active substance could be identified due to the unacceptable environmental risks for the spray application at the BPC 6 meeting, the eCA was requested to assess the watering can scenario. The watering can scenario was not evaluated before as it was considered a marginal use.

The rapporteur reported on the assessment of the watering can scenario that had been included into the assessment report. Also with this exposure scenario no safe use could be identified as risks for the soil compartment remained.

The rapporteur informed participants that in the meantime the applicant had submitted a revised scenario for the spray application which includes composting, and leads to a safe use for specific poultry stables.

Even though submitted very late in the process, the rapporteur evaluated the provided scenario and reported their conclusions. Due to risks for the soil compartment the rapporteur concluded that a safe use could be demonstrated only if the application rate was reduced from four per year to one, noting the default to be used according to the Emission Scenario Document is four.

Members explained that the dossier was already discussed at the last meeting and the revision would be limited to the inclusion of the watering can scenario. Members agreed that the level of technical detail of the revised scenario for the spraying application requires examination by the BPC WG - Environment. A member questioned whether the active substance is still efficacious at the reduced application rate.

Therefore the BPC concluded that the revised scenario for the spray application together with the comments from the eCA and ECHA should be consulted with the BPC

WG(s) before rescheduling the active substance product-type combination for further discussion at the BPC.

Actions:

SECR to:

- Launch a written consultation with the BPC WG - Environment to determine if the refined use submitted by the applicant can be considered as safe;
- Consider whether the Efficacy Working Group needs to be consulted due to the changed application frequency;
- Following the consultation round to schedule the substance/PT combination for one of the next BPC meetings.

7.3 Draft BPC opinion on glutaraldehyde for PT 2

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 Chair remarked that the active substance is considered a candidate for substitution and therefore a public consultation had taken place where comments had been received. These inputs had been included in the CAR and in the draft opinions. The Chair also informed members that a document (CA-Sept14-Doc.8. – 'Product-types of biocides used in the drilling sector') had been discussed and agreed at the Biocides CA meeting describing the assignment of relevant PTs for biocides used in the drilling sector. The eCA confirmed that that document did not influence the risk assessment, since it had been performed according to the uses and was independent of the assignment of PTs.

The rapporteur introduced the glutaraldehyde dossier and described the active substance. The consolidated AR including issues relevant to all the different PTs for discussion, was considered at the beginning of the meeting.

A member expressed concern about the use of an $AEC_{inhalation}$ (122 ppb) value in the human health risk characterisation, which was approximately 5 times higher than the concentration where respiratory sensitisation has been reported to have occurred in humans (20-30 ppb), to establish that risks were acceptable. To address this concern, it was agreed that a qualitative local risk assessment to address the potential for respiratory sensitisation following exposure shall be performed at the product authorisation stage.

A number of editorial comments and clarifications to be included in the AR were discussed and agreed. It was suggested that the efficacy section should be PT-specific, addressing the groups of target organisms in each opinion and in the AR. The need to perform, where relevant, a dietary risk assessment was agreed to be included in section 2.4 of the opinions for PTs 3, 4, 6 and 12. The consolidated AR for glutaraldehyde for all the PTs was agreed by the BPC, subject to the changes agreed during the meeting.

After the agreement on the AR, the general comments relevant for all the opinions were discussed. The efficacy section of the opinions was to be revised in order to address the specific target organisms or group of species relevant for each PT.

A proposal to include a specific provision on treated articles due to the potential for skin sensitisation of glutaraldehyde was discussed. This provision would be added as a standard provision and its relevance would be discussed by PT.

COM proposed to include more PT-specific information and address the quality of the outcome received during the public consultation in order to collect useful information for the product authorisation stage. Several members agreed that more information

would be useful for product authorisation and it was agreed that the information on the comments received would be addressed specifically by PT, including whether comments had been received on the essentiality of the active substance for the control of certain target organisms and the existence of other substances approved for the same use. It was concluded that a separate confidential annex will be added to the AR to include an overview of the information and the documents received.

After the discussion of the comments relevant for all the opinions, the PT-specific issues were discussed before the adoption of each individual opinion.

The BPC discussed the opinion on glutaraldehyde for use in PT 2. It was clarified that the use restriction to mopping only was due to the application time (110 minutes) for this type of application. Two members clarified that this risk mitigation measure is feasible and can be put in place. Therefore section 2.3.5 should state that products cannot be applied by wiping unless it can be demonstrated at product authorisation that there is no unacceptable risk.

In the scenario of accidental exposure to a child, one member proposed to include a re-entry time to allow surfaces to dry. This condition was to be included in section 2.4 of the opinion. The calculations provided by the applicant and the rapporteur showed that a re-entry time of 20 minutes would be sufficient to allow surfaces to dry so there would not be risk for skin and respiratory sensitisation. These new calculations were to be provided in the AR.

COM remarked that requirements for further information should be provided with the application for approval or during the evaluation in order to avoid any issues at product authorisation.

The BPC adopted by consensus its opinion on an application for the approval of the active substance glutaraldehyde for use in PT 2. The substance is considered a candidate for substitution in accordance with Article 10(1)(b) of the BPR.

Actions:

- Rapporteur: to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 13 November;

- 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 23 October and publish it on the ECHA website.

7.4 Draft BPC opinion glutaraldehyde for PT 3

The applicants for this active substance/PT combination remained the same as in 7.3 above and the Chair noted that the applicants had not objected to the presence of ASOs during the discussion.

Since the discussion on the consolidated AR including all PTs had taken place during the discussion of the opinion for PT 2, the AR was considered agreed for PT 3. The general comments on the opinions applicable for all PTs were to be taken into account for the revision on the opinion for PT 3. Therefore, only the comments specifically addressing the opinion on PT 3 were addressed.

As described in section 7.3 above the efficacy section was to be revised to check and address the target organisms and groups of species relevant for PT 3. It was agreed to include the term 'trained' when referring to the scenario of professionals fogging a farm in Section 2.1 and a specific provision that fogging should be restricted to trained professionals in Section 2.3.

It was agreed that the direct release to the environment from the scenario: laying hens in free range with litter floor, should be considered when authorising products in section 2.4, since according to one member, emissions via a sewage treatment plant might not be considered as a general case for poultry livestock.

A member remarked that the re-entry time (two hours) stated in section 2.4.5 should not only apply to children, but in all cases. This proposal was agreed by the BPC members. The specific provision on treated articles was considered relevant for PT 3 and will be included in the opinion in Section 2.3. The need to perform a quantitative local risk assessment for sensitisation was also to be added in section 2.4 of the opinion.

The BPC adopted by consensus its opinion on an application for the approval of the active substance glutaraldehyde for use in PT 3. The substance is considered a candidate for substitution in accordance with Article 10(1)(b) of the BPR.

Actions:

- Rapporteur to revise the AR in accordance with the discussions in the BPC and submit to the SECR by 13 November;

- 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 23 October and publish it on the ECHA website.

7.5 Draft BPC opinion on glutaraldehyde for PT 4

The applicants for this active substance/PT combination remained the same as in 7.3 above and the Chair noted that the applicants had not objected to the presence of ASOs during the discussion.

Since the discussion on the consolidated AR including all PTs had taken place during the discussion of the opinion for PT2, the AR was considered agreed for PT 4. The general comments on the opinions applicable for all PTs should also be taken into account for the revision on the opinion for PT 4. Therefore, only the comments specifically addressing the opinion on PT 4 were addressed.

The efficacy section will be revised to check and address the target organisms and groups of species relevant for PT 4. It was clarified that algae are not target organisms for the intended use in PT 4. The eCA pointed out that in the scenario: application of disinfectant in a slaughter house, PPE is needed due to sensitisation and this will be included in the table in section 2.1c.

Secondary exposure was not assessed since the potential for secondary exposure was very low. Since the application of the substance takes place at the end of the working day, the exposure to glutaraldehyde the following day will be insignificant. An explanation of the irrelevance for secondary exposure will be added in the AR and the opinion. It was agreed that the possibility to introduce a re-entry time was to be considered at the product authorisation stage and should be included in section 2.4 of the opinion.

The BPC adopted by consensus its opinion on an application for the approval of the active substance glutaraldehyde for use in PT 4. The substance is considered a candidate for substitution in accordance with Article 10(1)(b) of the BPR.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 13 November;

- 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 23 October and publish it on the ECHA website.

7.6 Draft BPC opinion on glutaraldehyde for PT 6

The applicants for this active substance/PT combination remained the same as in 7.3 above and the Chair noted that the applicants had not objected to the presence of ASOs during the discussion.

Since the discussion on the consolidated AR including all PTs had taken place during the discussion of the opinion for PT 2, the AR was considered agreed for PT 6. The general comments on the opinions applicable for all PTs should also be taken into account for the revision on the opinion for PT 6. Therefore, only the comments specifically addressing the opinion on PT 6 were addressed.

A request to describe in more detail the intended use for paper wet-end preservation and paper coating preservation was agreed to be included in section 2.1b of the opinion.

It was agreed that the efficacy section will be revised in order to check and address the target organisms and groups of species relevant for PT 6.

The eCA clarified that the potential risk for respiratory or skin sensitisation is covered by the generic concentration limit of 0.1%. A clarification of this aspect will be added in section 2.1c of the opinion.

The specific provision on maximum residue limits (MRLs) in section 2.3 will be moved to an element to be taken into account at product authorisation (section 2.4), where a dietary risk assessment will need to be performed, where relevant.

A discussion took place on the need to restrict the use of consumer products treated with a biocidal product containing glutaraldehyde. A member proposed that since the use of an in-can preservative by non-professional users had not been assessed there was no need to put a restriction on those uses. Several members considered that the provision on labelling treated articles (section 2.3.7) does not forbid the use by non-professionals and therefore a provision to restrict the use for non-professionals at concentrations of glutaraldehyde higher that 0.1%, unless safe use can be demonstrated by other means than PPE would be required. COM remarked that this specific element might be further discussed at the Commission level after the endorsement of the opinion since for other kind of products this limitation is not usually applied. Some members considered that this provision had not been included for other skin sensitiser PT 6 substances and for consistency should not be included for this active substance. A proposal by one member to add a specific provision as follows was supported to be included in Section 2.3 by the majority of the BPC members: glutaraldehyde shall not be used in treated articles, or in biocidal products intended for non-professional users at a concentration equal to or higher than 0.1% unless safe use can be demonstrated by other means than PPE.

The need to reuse or remove as hazardous waste the drilling and cementing fluids was not considered appropriate since the usual practice is to reuse the fluids for economic reasons and because the potential release has a water-based composition with low

risk from these fluids. This sentence was removed from Section 2.1c. The monitoring provision was not considered relevant.

The BPC adopted by consensus its opinion on an application for the approval of the active substance glutaraldehyde for use in PT 6. The substance is considered a candidate for substitution in accordance with Article 10(1)(b) of the BPR.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 13 November;
- 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 23 October and publish it on the ECHA website.

7.7 Draft BPC opinion on glutaraldehyde for PT 11

The applicants for this active substance/PT combination remained the same as in 7.3 above and the Chair noted that the applicants had not objected to the presence of ASOs during the discussion.

Since the discussion on the consolidated AR including all PTs had taken place during the discussion of the opinion for PT 2, the AR was considered agreed for PT 11. The general comments on the opinions applicable for all PTs should also be taken into account for the revision on the opinion for PT 11. Therefore, only the comments specifically addressing the opinion on PT 11 were addressed.

A request to describe in more detail the intended use for hydro testing water and oilfield injection water was agreed to be included in section 2.1b of the opinion. The efficacy section will be revised to check and address the target organisms and groups of species relevant for PT 11.

The eCA clarified that for the bystander exposure scenario, dermal exposure had not been assessed since the exposure potential was considered low. The request from one member to include a clarification on this issue in the opinion was agreed by the rapporteur.

The eCA proposed to include a condition: products shall not be authorised for the preservation of hydro testing water unless it can be demonstrated that the product will not lead to an unacceptable risk. This was accepted. It was clarified by a member that the direct release to seawater was lower for the oilfield injection water than in the hydro testing water scenario, which leads to different outcomes of the assessments.

As proposed by the eCA, the term 'small' shall be maintained in specific condition 2.3.5 making reference to the exposure assessment used in the evaluation.

The BPC adopted by consensus its opinion on an application for the approval of the active substance glutaraldehyde for use in PT 11. The substance is considered a candidate for substitution in accordance with Article 10(1)(b) of the BPR.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 13 November;
- 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 23 October and publish it on the ECHA website.

7.8 Draft BPC opinion on glutaraldehyde for PT 12

The applicants for this active substance/PT combination remained the same as in 7.3 above and the Chair noted that the applicants had not objected to the presence of ASOs during the discussion.

Since the discussion on the consolidated AR including all PTs had taken place during the discussion of the opinion for PT2, the AR was considered agreed for PT 12. The general comments on the opinions applicable for all PTs should also be taken into account for the revision on the opinion for PT 12. Therefore, only the comments specifically addressing the opinion on PT 12 were addressed.

Upon request of a member, the efficacy section will be revised to check and address the target organisms and groups of species relevant for PT 12. A request to describe in more detail the use as a wet-end slimicide and paper de-inking slimicide was agreed to be included in section 2.1b of the opinion.

The need for PPE in scenario: cleaning/maintenance of pulp tanks and exposure to paper mill white water due to sensitisation properties of the substance will be clarified in the text below the table in section 2.1c of the opinion. A member requested to include in Section 2.4.6 that respiratory protective equipment (RPE) is needed unless risk can be mitigated by other means.

The SECR asked for clarification on the differences in the risk assessment for seawater and freshwater scenarios. The PNECseawater is 10 times lower than the PNECfreshwater due to the different dilution factors. The rapporteur proposed to include a provision that products shall not be authorised for the use in pulp or paper mills which are not connected to waste water treatment plants unless it can be demonstrated that products will not present unacceptable risk, which was agreed by the members.

Two members proposed to include the MRL provision for PT 12. Since the possibility of residues in food and feed cannot be excluded, the need to perform, where relevant, a dietary risk assessment was agreed to be included in section 2.4 of the opinion for PT 12.

The BPC adopted by consensus its opinion on an application for the approval of the active substance glutaraldehyde for use in PT 12. The substance is considered a candidate for substitution in accordance with Article 10(1)(b) of the BPR.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 13 November;

- 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 23 October and publish it on the ECHA website.

7.9 Draft BPC opinion on clothianidin for PT 18

The Chair welcomed the applicants and their accompanying experts for this item. The Chair noted that the applicants had not objected to the presence of ASOs during the discussion.

In relation to the applicability of an environmental exposure scenario document (ESD) at the product authorisation stage it was explained that it will only be a revision, if deemed necessary related to a specific issue in the ESD. A related consultation by the Ad hoc WG - Environmental Exposure is to be launched and the issue is intended to be settled by the end of 2014.

The assessment report was agreed subject to the minor modifications described in the open issues table.

Given the concern for potential impact of neonicotinoids on bees, the eCA agreed to add more explanation on the assessment of bees in the opinion.

The risk of domestic use products to the environment was discussed. For the assessed specific domestic product use the exposure of the environment was negligible and therefore no potential risk was identified.

A member requested to delete (2.4 of the opinion) the restriction proposed on the product size for non-professionals to 0.5 L as it was not linked to the risk assessment and because it was specific to the representative product of the dossier. The restriction was deleted.

A member proposed not to subordinate the risk assessment for bees at the product authorisation stage, depending of the availability or not of an agreed assessment concept. Indeed, due to the importance of bees and this group of active substances, each member state might have the possibility to perform a risk assessment for bees, even if no agreed assessment concept is available at this time. The eCA proposed a new wording taking into account this proposal.

The BPC adopted by consensus its opinion on an application for the approval of the active substance clothianidin for use in PT 18.

The substance is considered a candidate for substitution in accordance with Article 10(1)(d) of the BPR.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 13 November;
- 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 23 October and publish it on the ECHA website.

7.10 Draft BPC opinion on MIT for PT 13

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.

Following the introduction of the active substance by the rapporteur, the AR was presented for discussion. The AR was agreed with minor modifications as reflected in the open issues table.

A member commented that the specific concentration limit (SCL) should be 15 ppm in the classification proposal instead of 600 ppm. However, it is in the scope of RAC to set the SCL based on the available information.

A position paper submitted by the member from SE was tabled as a room document shortly before the meeting and was discussed. As MIT is a potent sensitiser used in a wide range of treated articles, many in consumer use, and there is a growing number of reports on sensitisation, SE proposed to flag MIT as a candidate for substitution according to 10(1)(e) of the BPR. Though the concern is raised in particular for PT 6,

SE considered that the substitution criterion is not PT-specific thereby it needs to be flagged at the first product-type under evaluation.

The concern for sensitisation was widely shared, in particular for PT 6 applications. Yet, many members interpreted Article 10(1)(e) as a use-specific criterion, which is exposure and use pattern based. For the evaluated PT 13 use the criterion is not met. Many members considered that the criterion could still apply for PT 6 even if for PT 13 it is not considered relevant. The ongoing policy discussion at the Biocides CA level on how to apply some of the substitution criteria listed in Article 10(1), including the criterion (e), was emphasised.

For PT 13 the intended use evaluated was for industrial/professional use where appropriate risk management measures (RMMs) and operational procedures are in place limiting the potential exposure to the active substance. Nonetheless it was emphasised that the use of gloves is not possible during the whole handling procedure due to safety considerations: the use of MIT in PT 13 is not in all cases fully automated meaning that professional users may be exposed as there are situations where it is not possible for professionals to wear gloves to protect them from exposure on grounds of safety when using machinery.

A member proposed an alternative approach to deal with isothiazolones: setting a concentration limit for all end-use products (biocidal products and treated articles) used by the general public, instead of considering them as candidate for substitution. This concentration limit could also be relevant for professional uses when other protective measures are not sufficient to avoid potential exposure. This member indicated that this approach was proposed for the risk assessment of another isothiazolone of which it is eCA, and which raises the same concerns as MIT. It was added that during the commenting period on the CAR of this active substance, some member states supported this approach. However, they questioned the applicability of such a measure.

The applicant commented that according to their interpretation the criterion is risk and not hazard-based; specific uses could be excluded at the product authorisation stage if risks are identified.

An ASO raised the impact for down-stream users when the use of an in-can preservative is restricted. If the use of one will decrease, the use of another, potentially with other reasons for concern, will increase. A holistic approach needs to be taken for actives in PT 6 and be discussed at policy level at the CA meeting.

The SECR noted that from a procedural point of view, due to strict time constraints, it is difficult to flag an active as a candidate for substitution at the BPC meeting; there will not be sufficient time to launch a public consultation. A member pointed out that this is a circumstance that ECHA and the Commission will have to take into account since it is always possible that an active substance that has not been identified as a potential candidate for substitution by the eCA is identified as such during WG discussions.

It was concluded that the issue is recommended to be considered when the discussion on the development of related guidance on substitution criteria takes place and a decision is taken on the approval of the active substance for PT 13.

Related to potential non-professional use applications an element to be considered at product authorisation was added. It highlights that the RAC opinion shall be taken into account and that biocidal products that trigger classification as skin sensitisers, category 1A shall normally not be authorised for non-professional uses.

The potential requirement for additional monitoring data was also discussed. A member commented that there was no clear agreement in the BPC WGs or from discussions at the former technical meeting on tier 2 calculations for the environment.

The member proposed to request monitoring data if safe use cannot be identified at the tier 1 level.

The current ESD for PT 13 is under revision. The main reason behind this revision is that the ESD leads to an unrealistic worst case assessment of the environmental exposure following the use of metal working fluids (MWF). At the BPC WG - Environment it was decided to use the intermediate results (if an unacceptable risk is identified applying the current ESD) of the ongoing revision as prepared by the Fraunhofer Institute.

The BPC agreed for tier 2 calculations to use transitionally the following parameters:

- A dilution factor of 100 for dilution between the company to the external STP;
- A dilution factor of 100 from the STP to the surface water; and
- A factor of relevance of 0.5.

This applies to dossiers submitted before 1 September 2013. The BPC WG - Environment is requested to confirm the above mentioned approach.

As for monitoring data a member commented that the end users should not be requested to perform monitoring; though it will be useful information to establish the dilution factors, it is substance-dependant. It was added that the monitoring data is specific to the process of manufacturing of the product and it may be used in different ways. Likewise, the difficulty of determining sources for sampling was also noted. The element related to monitoring data in the opinion was modified accordingly.

After some discussion the condition of end use concentrations in metal working fluids was moved to elements to be taken into account.

The BPC adopted by majority its opinion on an application for the approval of the active substance MIT for use in PT 13. One member did not support the opinion and therefore had a minority position. Another member noted that a pre-requisite for their support is that the BPC WG - Environment confirms the approach taken for tier 2 calculations related to PT 13.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 13 November;
- Member to provide its minority position in writing to the SECR by 10 October;
- 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 23 October and publish it on the ECHA website.

7.11 Draft BPC opinion on MBM for PT 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.

Following the introduction of the active substance by the rapporteur, the AR covering both PT 6 and PT 13 was discussed.

A member questioned whether the BPC WG – Human Health can decide to apply a threshold approach for carcinogenicity of formaldehyde, as it has done in this case when it also has applications in other legislative areas e.g. plant protection products. However, after discussion the assessment was considered to be a technical and scientific issue for which the WG is regarded as the appropriate forum. The WG has

considered both the formaldehyde core dossier as well as the RAC opinion in their discussion.

The exposure of the general public to a carcinogen category 1B substance was also discussed. The representative use in fuels was considered safe even without wearing gloves or other PPE. The applicant noted that dispensing of fuels to the general public in fuel service stations are highly regulated e.g. requiring RMM such as petrol vapour recovery. The applicant stated that the only intended use of MBM in PT 6 is preservation of fuels.

The assessment report was therefore agreed with minor modifications.

The general issues relating to both PT 6 and PT 13 opinions were discussed before going to the PT-specific issues.

During the discussion it was also noted that the naming of the active substance is pending the outcome of the discussions on the guidance for *in situ* generated substances. This will be considered when a decision is taken on the approval of the active substance.

The following PT 6-related key issues were discussed.

It was discussed whether exposure to MBM in fuel should be considered primary or secondary exposure. In terms of exposure of MBM through its use as a biocidal active substance, this is a secondary exposure scenario. If the scenario is exposure to MBM present in a treated article, this can be considered as primary exposure. For consistency in similar scenarios in future BPC opinions, it should be made clear what the term primary exposure refers to.

Another issue raised was whether an additional statement is needed to underline that though for the assessed use the use of gloves is not required, for potential other treated articles this may not be the case. The cause of concern was related to the carcinogenic potential of the released formaldehyde. The applicant supported adding a statement that at the fuel station standard technology is sufficient, no PPE is required, but for any other uses dermal exposure should be avoided. However, it was agreed not to add such a statement since this relates to the assessed use but the statement would be generally applicable to any use applied for following approval.

The need of specific provisions on treated articles related to sensitisation, meeting the exclusion criteria (carcinogenicity) and use by non-professionals was discussed in detail. The possibility of restricting dermal exposure for other treated articles than fuels was investigated. Regarding fuels, taking into account the outcome of the assessment of the active substance dossier, it was commonly supported that no labelling for sensitisation or carcinogenicity is required. Concerning sensitisation, for consistency with the catalogue of standard phrases based on MSCA guidance for approval, it was decided to add the standard provision on labelling in the proposed conditions for approval.

However, some members sought specific conditions – similarly as labelling for the sensitisation properties – to limit or warn about dermal exposure to formaldehyde via treated articles. Concern was raised in particular for treated articles other than fuels; especially in view of imported treated articles that are not assessed at product authorisation. However, it was suggested by a member that the concern for carcinogens might be different compared to sensitisers as the hazard and the response to exposure might be different. After a long discussion it was agreed not to add a specific condition on the carcinogenic effect to the BPC opinion.

Reservations were expressed in applying the same labelling provisions for carcinogenicity as for sensitisation. While the CLP regulation applies for mixtures, for other treated articles exposure will be dependent on migration. A member commented that PT 6 is related to mixtures unlike PT 9, therefore the discussions are

related to treated articles being mixtures only in this case. One member also wondered whether at this stage it can be decided if the active substance will only be used for the preservation of fuels or other mixtures or if it will be incorporated in other treated articles not considered as mixtures.

It was mentioned that not having a harmonised classification for the active substance makes it especially difficult to set provisions. Nonetheless, in response to a comment from a member it was acknowledged that if there is concern provisions may be set. However, the risk assessment of the specific use did not indicate a concern; in principle, conditions are set when a risk was identified. The Biocides CA guidance allows setting conditions for treated articles when there is indication of major concern.

The eCA supported restricting the use to the assessed use only. However, other members stated that restricting other uses without assessing them and identifying risks is questionable, especially as Article 5(2) of the BPR does not apply for dossiers submitted before 1 September 2013.

With respect to the carcinogenic properties of MBM releasing formaldehyde and the use in treated articles of biocidal products containing MBM all options discussed were proposed by the BPC to be considered by COM in its decision-making process under Article 9(1) of the BPR. One member noted the proposed options did not address the issue of imported treated articles.

The BPC adopted by consensus its opinion on an application for the approval of the active substance MBM for its use in PT 6.

The substance is considered as a candidate for substitution in accordance with Article 10(1)(a) of the BPR.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 13 November;
- 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 23 October and publish it on the ECHA website.

7.12 Draft BPC opinion on MBM for PT 13

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 assessment report was agreed with minor modifications.

For the opinion the general issues related to MBM discussed earlier are relevant for MBM in PT 13. However, it was decided that the provision for treated articles related to skin sensitisation is not required for PT 13. In section 2.3(6) the word 'undiluted' and the second element in section 2.4 was agreed to be removed.

The BPC adopted by consensus its opinion on an application for the approval of the active substance MBM for its use in PT 13.

The substance is considered as a candidate for substitution in accordance with Article 10(1)(a) of the BPR.

Actions:

- Rapporteur to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR by 13 November;

- 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 23 October and publish it on the ECHA website.

7.13 Draft BPC opinion on *Pythium oligandrum* for PT 10

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.

Following the introduction of the active substance by the rapporteur, the AR was discussed.

The most critical issue was the risk assessment related to sensitisation, in particular related to non-professional uses. For the brushing scenario, a member requested to address the potential of aerosol formation. Members commented that exposure to microbial active substances that may provoke sensitising reactions by non-professionals should be minimised by means other than the use of PPE. Some members agreed with the eCA proposal to compare the concentrations of the microbial active substance in the product with the specific concentration limits established for chemicals classified as sensitisers. An adviser commented that the low concentration of the microorganism in the water suspension would mean that the suspension should not be considered sensitising; but exposure would be still possible for the powder formulation. Use of water soluble sachets, for example, by non-professionals would also be a possible RMM.

A member indicated that the qualitative risk assessment performed for the environment (scenario of disposal of unused biocidal product after treatment via the sewer) was not discussed at the time of the TM and that the parameters chosen were questionable. Thus it was requested to add a provision in the opinion (2.4) to allow the revision of this assessment at product authorisation stage. Moreover, it was proposed to highlight (2.4) that walls should not be rinsed after application of the product, as it is a condition for efficacy of the treatment as well as for considering that exposure of the environment will be very low.

BPC members made a number of other comments on the draft assessment report. As a result it was concluded that the assessment report will need to be revised and sufficient time given to allow members to consider the changes. Accordingly, this substance will be scheduled for adoption at the next BPC meeting.

Actions:

- Rapporteur to revise the assessment report and if necessary the draft opinion in accordance with the discussions in the BPC and submit to the SECR by 24 October.

7.14 Revised draft BPC opinion on copper pyrithione PT 21

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.

It was explained why the opinion for copper pyrithione PT 21 had to be revised following adoption at BPC-6: when finalising the assessment report after the BPC-6 it was found out by the evaluating Competent Authority Sweden that the acceptable exposure limit (AEL) dermal short term AEL of 0.005 mg/kg bw/day was not used consistently in the evaluation. The risk calculations for the two products intended for amateur use therefore had to be updated. When the value of 0.005 was used instead of 0.02 mg/kg bw/day, the paint application scenario leads to an unacceptable risk.

This meant that the BPC opinion adopted at the BPC-6 meeting had to be changed and a revised opinion was scheduled for adoption at this meeting. The revised AR was presented for discussion and agreed with a minor modification.

The applicant presented their comments expressing their concern related to the decisions made and the process taken. In particular, the applicant argued that they had not been provided with sufficient time to react to critical changes in the AR. It was emphasised that other EU evaluating bodies, including national authorities and the Scientific Committee on Consumer Safety had come to different conclusions. The applicant claimed that despite that the pyrithiones are a very data rich series of compounds the evaluation focused on atypical findings. Moreover, the applicant pointed to the derivation of the short-term dermal AEL: this value is set equal to the oral value leading to the fundamental question: why is the short term dermal AEL lower than the oral acute reference dose (ARfD). For this the applicant could not find an explanation in the AR and challenged this conclusion. The applicant stated they reserve the right to consider further actions as may be necessary to redress the situation.

The BPC adopted by consensus the revised opinion on an application for the approval of the active substance copper pyrithione for its use in PT 21.

Actions:

- Rapporteur to revise the AR in accordance with the discussions in the BPC and submit to the SECR by 13 November;
- 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 23 October and publish it on the ECHA website.

8. Establishing technical equivalence and chemical similarity

8.1 Technical equivalence for multiple dossiers

The SECR introduced document BPC-7-2014-03. BPC members agreed document BPC-7-2014-03 subject to the clarification that the identity of the substances need to be confirmed as the same before the data can be combined into one single CAR and List of Endpoints (LoEP). It was discussed how to combine data from different applicants into the LoEP where it was considered crucial that it is indicated in the LoEP which value for a certain endpoint has to be used for product authorisation. In principal this will be the most critical value but this is not necessarily the case. Combining the data into one LoEP may require some additional work of the eCA after the active substance is approved. It was not considered necessary to indicate the applicant who submitted the study on which the value for a certain endpoint is based. It was noted by one member that if applicants share information via a letter of access, combining data into one LoEP may not always be that straightforward.

Actions:

- SECR to make the agreed changes and upload the final document to the BPC CIRCABC after the meeting.

9. Any other business

9.1 Union authorisation pre-submission phase

The BPC discussed the need to request detailed information on uses, related instructions and label claims and concluded that the draft summary of product

characteristics (SPC) should be adequate provided that it contains sufficiently detailed information on uses.

The SECR indicated that it will request additional data from the applicant for the first pre-submission consultation and that a second round of MSCA consultations will take place. The additional data is to further specify the uses and provide clearer information on the existing products authorised or notified at national level.

Actions:

- SECR to go back to the applicant to request further information with a clear timeline.

10. Agreement of the action points and conclusions

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

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Part II – Main conclusions and action points

Agreed on 3 October 2014 at the 7th meeting of BPC

30 September – 3 October 2014

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.	**SECR:** to upload the agreed final agenda to the BPC CIRCABC as part of the draft meeting minutes after the meeting.
Item 4 - Agreement of the minutes and review of actions from BPC-6	
The revised version of the minutes of BPC-6 was agreed as proposed.	**SECR:** to upload the agreed minutes to the BPC CIRCABC and to the ECHA website after the meeting.
Item 5 - Administrative issues	
5.2 Other administrative issues	
Substance documents	**SECR** to: • To ensure documents in CIRCABC have titles that correspond to the document name; • To upload the final version of the open issue documents (with outcomes of the discussions included) to the BPC CIRCABC after the meeting, following an editorial check by the SECR.
Item 6 - Work programme for BPC for 2014 – 2015	
	SECR: to consider updating the CLH/PBT overview table with RAC planning information, where available. **Members:** to send information on any changes to the Work Programme (WP) to the SECR. **SECR:** to update the WP in the light of the information from members and upload the revised document to the BPC CIRCABC and the ECHA web site after the meeting. The WP is to be updated after each meeting, where appropriate.
Item 7 - Applications for approval of active substances	
7.1 Working procedure and templates: update from SECR	

7.1a New data generated after active substance approval Technical equivalence is considered as a condition to include data from third party dossiers. Clarification is needed for which cases and how data from third party dossiers will be incorporated in the List of Endpoints (LoEPs). The LoEPs is not to be updated too frequently, but if additional data has legal consequences at the product authorisation stage a formal mechanism to approve the amended LoEPs incorporating the new data will be required.	**Members:** to provide comments in writing **by 24 October** in the dedicated CIRCABC newsgroup. **SECR:** to prepare a revised document for the next meeting which includes a clarification for which cases and how data from third party dossiers will be incorporated in the LoEPs.
7.1b Catalogue of standard phrases for active substance approval	**Members:** to apply the standard phrases in future draft opinions. **SECR:** to upload the catalogue to the BPC CIRCABC after the meeting and update after each meeting, where appropriate.
7.2 Draft BPC opinion on triflumuron for PT 18	
The BPC discussed the refined use scenario provided by the applicant to demonstrate a safe use following the request at BPC-6. It was concluded that due to its technical content, a review will be requested from the ENV working group.	**SECR** to: • Launch a written consultation with the ENV working group to determine if the methodology applied to refine the use scenario submitted by the applicant can be accepted; • Consider whether the Efficacy Working Group needs to be consulted in case the application frequency will be one per year; • Following the consultation round to schedule triflumuron for one of the next BPC meetings.
7.3 Draft BPC opinion on glutaraldehyde for PT 2	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. The substance is considered a candidate for substitution in accordance with Article 10(1)(b) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 13 November**. **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 23 October** and publish it on the ECHA website.
7.4 Draft BPC opinion on glutaraldehyde for PT 3	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 13 November**.

The substance is considered a candidate for substitution in accordance with Article 10(1)(b) of the BPR.	**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 23 October** and publish it on the ECHA website.
7.5 Draft BPC opinion on glutaraldehyde for PT 4	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. The substance is considered a candidate for substitution in accordance with Article 10(1)(b) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 13 November**. **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 23 October** and publish it on the ECHA website.
7.6 Draft BPC opinion on glutaraldehyde for PT 6	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. The substance is considered a candidate for substitution in accordance with Article 10(1)(b) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 13 November**. **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 23 October** and publish it on the ECHA website.
7.7 Draft BPC opinion on glutaraldehyde for PT 11	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. The substance is considered a candidate for substitution in accordance with Article 10(1)(b) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 13 November**. **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 23 October** and publish it on the ECHA website.

7.8 Draft BPC opinion on glutaraldehyde for PT 12	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. The substance is considered a candidate for substitution in accordance with Article 10(1)(b) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 13 November**. **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 **23 October** and publish it on the ECHA website.
7.9 Draft BPC opinion on clothianidin for PT 18	
The BPC adopted by consensus its opinion on an application for the 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 13 November**. **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 **23 October** and publish it on the ECHA website.
7.10 Draft BPC opinion on MIT for PT 13	
The BPC adopted by majority its opinion on an application for the approval of this active substance/PT combination. One member did not support the opinion.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 13 November**. **Member:** to provide its minority position in writing to the SECR **by 10 October.** **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 23 October** and publish it on the ECHA website. **SECR:** to request the BPC WGs to strengthen their minutes in particular to clarify agreements that have been reached.
7.11 Draft BPC opinion on MBM for PT 6	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 13 November**.

The substance is considered as a candidate for substitution in accordance with Article 10(1)(a) of the BPR.	**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 **23 October** and publish it on the ECHA website.
7.12 Draft BPC opinion on MBM for PT 13	
The BPC adopted by consensus its opinion on an application for the approval of this active substance/PT combination. The substance is considered as a candidate for substitution in accordance with Article 10(1)(a) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 13 November**. **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 23 October** and publish it on the ECHA website.
7.13 Draft BPC opinion on *Pythium oligandrum* M1 for PT 10	
BPC members made a number of comments on the draft assessment report. As a result it was concluded that the assessment report will need to be revised and sufficient time given to allow members to consider the changes. Accordingly, this substance will be scheduled for adoption at the next BPC meeting.	**Rapporteur:** to revise the assessment report and if necessary the draft opinion in accordance with the discussions in the BPC and submit to the SECR **by 24 October**.
7.14 Revised draft BPC opinion on copper pyrithione PT 21	
The BPC adopted by consensus the revised opinion on an application for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 13 November**. **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 23 October** and publish it on the ECHA website.
Item 8 – Establishing technical equivalence and chemical similarity	
8.1 Technical equivalence for multiple dossiers	
BPC members agreed document BPC-7-2014-03 subject to the clarifications that the identity of the substances need to be confirmed as the same and that data sets will be combined when there are multiple applicants and to indicate	**SECR:** to make the agreed changes and upload the final document to the BPC CIRCABC after the meeting.

which value for an endpoint was used in the evaluation.	
Item 9 – AOB	
9.1 Union authorisation pre-submission phase	
The BPC discussed the need to request detailed information on uses, related instructions and label claims and concluded that the draft SPC should be adequate provided that it contains sufficiently detailed information on uses. The SECR indicated that it will request additional data from the applicant for the first pre-submission consultation and that a second round of MSCA consultation will take place. The additional data is to further specify the uses and provide clearer information on the existing products authorised or notified at national level.	**SECR:** to go back to the applicant to request further information with a clear timeline.

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Part III - List of Attendees

Members	Advisers
BERTAGNA Pierre-Loic (FR)	AZDAD Karima (BE)
COSTIGAN Michael (UK)	COLLET Romy (FR)
CZAKÓ Klára Mária (HU)	CRESTI Raffaella (IT)
DONS Christian (NO)	ČEBAŠEK Petra (SI)
DRAGOIU Mihaela-Simona (RO)	HÄMÄLÄINEN Anna-Maija (FI)
GONZÁLEZ MÁRQUEZ María Luisa (ES)	JÄGER Stefanie (DE)
HARRISON John (IE)	KARHI Kimmo (FI)
HEESCHE-WAGNER Kerstin (DE)	KOIVISTO Sanna (FI)
IAKOVIDOU Mary (SE)	KOMEN Corine (NL)
LARSEN Jørgen (DK)	LÖFBOM Johanna (SE)
MAJUS Saulius (LT)	MIKOLAS Jan (CZ)
MERISTE Anu (EE)	PALOMÄKI Jaana (FI)
MIKOLASKOVA Denisa (SK)	PLATTNER Edmund (AT)
NELEMANS Maartje (NL)	VOMASTKOVÁ Milada (CZ)
RUBBIANI Maristella (IT)	
TERNIFI Vesna (SL)	**Accredited Stakeholder Organisations**
TUUSA Tiina (FI)	BRUYNDONCKX Raf (CEFIC)
VACEK Tomas (CZ)	CAZELLE Elodie (AISE)
VAN BERLO Boris (BE)	LEROY Didier (CEPE)
ZIGRAND Jeff (LU)	
ZOUNOS Athanassios (EL)	
	ECHA Staff
Alternate members	FURHMANN Anna
CHROBAK Robert (PL)	ESTEVAN MARTINEZ Carmen
GAVRIEL Alexandros (CY)	HOLLINS Steve
KECK Marianne (AT)	JANOSSY Judit
TURK Rajka (HR)	MATTHES Jochen
	NEGULICI Ligia
European Commission	VAN DE PLASSCHE Erik
CHATELIN Ludovic	

Applicants	Apologies
BLONDAZ Pascal (Bayer) for Triflumuron	BROVKINA Julija (LV)
BUCHERT Pascale (Dow Benelux BV) for Glutaraldehyde	BUSUTTIL Ingrid (MT)
DURRER Stefan (BASF) for Glutaraldehyde	MARTINS DE ALMEIDA Ines Filipa (PT)
GARTLAND Kevan (Sumitomo Chemical Plc) for Clothianidin	REID Kirsty (Eurogroup for Animals)
POPPLETON Jack (Lonza) for Copper pyrithione	
RUBÁK Petr (Biopreparáty spol. s r.o.) for *Pythium oligandrum*	
WATT Ian (Dow Chemical) for MIT	
WALTER Bernd (Thor GmbH) for MIT	
WRAGG Mick (Lubrizol) for MBM	
Experts accompanying applicants	
AHLFORD Kristina (accompanying GARTLAND Kevan) for Clothianidin	
BITSCH Annette (accompanying WRAGG Mick) for MBM	
FREEMANTLE Mike (accompanying POPPLETON Jack) for Copper pyrithione	
HINDLE Stuart (accompanying BUCHERT Pascale) for Glutaraldehyde and (accompanying WATT Ian) for MIT	
ROSSBACHER Roland (accompanying DURRER Stefan) for Glutaraldehyde	

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-7 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2	BPC-A-7-2014 rev 2	Draft agenda	
4	BPC-M-6-2014	Draft minutes from BPC-6	
6	BPC-7-2014-17	Revised Work Programme 2014-15	
7.1a	BPC-7-2014-01	New data generated after active substance approval	
7.1b	BPC-7-2014-02 rev 1	Catalogue of standard phrases for active substance approval	
8.1	BPC-7-2014-03	Technical equivalence for multiple dossiers in the active substance approval process	
9.1	BPC-7-2014-18	Information requirements for Union Authorisation pre-submission	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.2	BPC-7-2014-04A	Triflumuron-PT18	Draft opinion
	BPC-7-2014-04B		Draft assessment report
	BPC-7-2014-04C		Open issues
	BPC-7-2014-04D		BAYER Use pattern
	BPC-7-2014-04E		BAYER Comments on assessment Report
	BPC-7-2014-04F		eCA Comments on BAYER Assessment Report
	BPC-7-2014-04G		SECR comments on applicant paper
7.3	BPC-7-2014-05A	Glutaraldehyde-PT2	Draft opinion
7.3, 7.4 7.5, 7.6 7.7, 7.8	BPC-7-2014-05B	Glutaraldehyde-PT2, 3, 4, 6, 11 and 12	Draft assessment report - PT 2, 3, 4, 6, 11 and 12
	BPC-7-2014-05C		Open issues
7.4	BPC-7-2014-06A	Glutaraldehyde-PT3	Draft opinion
7.5	BPC-7-2014-07A	Glutaraldehyde-PT4	Draft opinion

7.6	BPC-7-2014-08A	Glutaraldehyde-PT6	Draft opinion
7.7	BPC-7-2014-09A	Glutaraldehyde-PT11	Draft opinion
7.8	BPC-7-2014-10A	Glutaraldehyde-PT12	Draft opinion
7.9	BPC-7-2014-11A	Clothianidin-PT18	Draft opinion
	BPC-7-2014-11B		Draft assessment report
	BPC-7-2014-11C		Open issues
7.10	BPC-7-2014-12A	MIT-PT13	Draft opinion
	BPC-7-2014-12B		Draft assessment report
	BPC-7-2014-12C		Note on new environmental exposure assessment
	BPC-7-2014-12D		Open issues
	BPC-7-2014-12E Room Document		SE position on MIT
7.11	BPC-7-2014-13A	MBM-PT6	Draft opinion
7.11	BPC-7-2014-13B	MBM-PT6 and 13	Draft assessment report - PT 6 and 13
7.12	BPC-7-2014-13C		Open issues
7.12	BPC-7-2014-14A	MBM-PT13	Draft opinion
7.13	BPC-7-2014-15A	Pythium oligandrum-PT10	Draft opinion
	BPC-7-2014-15B		Draft assessment report
	BPC-7-2014-15C		Open issues
7.14	BPC-7-2014-16A	Copper pyrithione-PT21	Revised draft opinion
	BPC-7-2014-16B		Revised assessment report
	BPC-7-2014-16B rev1		Revised assessment report (Track changes)
	BPC-7-2014-16C		Note of rapporteur
	BPC-7-2014-16D		Open issues

Annex II

BPC-A-7-2014 FINAL
Agreed at BPC-7
30 September 2014

Final agenda

7th meeting of the Biocidal Products Committee (BPC)

30 September – 3 October,

ECHA Conference Centre (Annankatu 18, Helsinki)

30 September: starts at 10:00

3 October: ends at 13:00

Item 1 – Welcome and apologies

Item 2 – Agreement of the agenda

BPC-A-7-2014 rev2

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-6

BPC-M-6-2014 rev 1

For agreement

Item 5 – Administrative issues

5.1 Housekeeping issues

For information

5.2 Other administrative issues

For information

Item 6 – Work programme for BPC for 2014 - 2015

BPC-7-2014-17

For information

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

7.1 Working procedure and templates: update from SECR

a) New data generated after active substance approval

BPC-7-2014-01

For discussion

b) Catalogue of standard phrases for active substance approval

BPC-7-2014-02 rev1

For information

7.2 Draft BPC opinion on triflumuron for PT 18

Previous discussion(s): BPC-6

BPC-7-2014-04 A,B,C,D,E,F,G

For adoption

7.3 Draft BPC opinion on glutaraldehyde for PT 2

Previous discussion(s): 2011 TM III, 2013 TM III

BPC-7-2014-05 A,B,C

For adoption

7.4 Draft BPC opinion on glutaraldehyde for PT 3

Previous discussion(s): 2011 TM III, 2013 TM III

BPC-7-2014-05 B,C & BPC-7-2014-06A

For adoption

7.5 Draft BPC opinion on glutaraldehyde for PT 4

Previous discussion(s): 2011 TM III, 2013 TM III

BPC-7-2014-05 B,C & BPC-7-2014-07A

For adoption

7.6 Draft BPC opinion on glutaraldehyde for PT 6

Previous discussion(s): 2011 TM III, 2013 TM III

BPC-7-2014-05 B,C & BPC-7-2014-08A

For adoption

7.7 Draft BPC opinion on glutaraldehyde for PT 11

Previous discussion(s): 2011 TM III, 2013 TM III

BPC-7-2014-05 B,C & BPC-7-2014-09A

For adoption

7.8 Draft BPC opinion on glutaraldehyde for PT 12

Previous discussion(s): 2011 TM III, 2013 TM III

BPC-7-2014-05 B,C & BPC-7-2014-10A

For adoption

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[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 issues for discussion (covering all PTs for that substance).

7.9 Draft BPC opinion on clothianidin for PT 18
Previous discussion(s): 2010 TM II

BPC-7-2014-11 A,B,C
For adoption

7.10 Draft BPC opinion on MIT for PT 13
Previous discussion(s): 2012 TM IV

BPC-7-2014-12 A,B,C,D,E
For adoption

7.11 Draft BPC opinion on MBM for PT 6
Previous discussion(s): WGIII 2014

BPC-7-2014-13 A,B,C
For adoption

7.12 Draft BPC opinion on MBM for PT 13
Previous discussion(s): WGIII 2014

BPC-7-2014-13 B,C & BPC-7-2014-14 A
For adoption

7.13 Draft BPC opinion on *Pythium oligandrum* for PT 10
Previous discussion(s):TMIV-2012

BPC-7-2014-15 A,B,C
For adoption

7.14 Revised draft BPC opinion on copper pyrithione PT 21
Previous discussion(s):BPC-6

BPC-7-2014-16 A, B,B rev1,C,D
For adoption

Item 8 – Establishing technical equivalence and chemical similarity

8.1 Technical equivalence for multiple dossiers

BPC-7-2014-03
For agreement

Item 9 – Any other business

9.1 Union authorisation pre-submission phase

BPC-7-2014-18
For discussion

Item 10 – Agreement of the action points and conclusions

For agreement

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