

31 May 2015 BPC-M-15-2016

Minutes of the 15th meeting of

the Biocidal Products Committee (BPC)

13 – 14 April 2016

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chairman of the Biocidal Products Committee (BPC) welcomed the participants to the 15th BPC meeting and informed the meeting that, following the membership renewal exercise launched in January 2016, the appointment of most BPC members was renewed. Three new members were appointed, representing Finland, Norway and Spain respectively, all attending the meeting. The Chairman also mentioned that eleven new alternate members have been appointed, of which four attending the meeting.

The Chairman informed the BPC members of the participation of 27 members, including seven alternates.

Five advisers, one invited expert and two representatives from accredited stakeholder organisations (ASOs) were present at the meeting. Two representatives from the European Commission attended the meeting via web conference. Apologies were received from three 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-15-2015_rev1) and indicated that it was decided to postpone the item 7.1.c) (template for the Assessment Report) to a future meeting, due to the comments received on the Assessment Report template and also due to the comments received on using the new CAR template from the Competent Authorities currently preparing evaluations.

To follow, the Chairman invited then any additional items. No additional item was suggested.

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

The Chairman informed the 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 conflict of interest in relation to the agreed agenda. None was declared.

4. Agreement of the draft minutes and review of actions arising from BPC-14

The revised draft minutes from BPC-14 (BPC-M-14-2016), incorporating the comments received from members, were agreed. The Chairman also noted that confidential minutes for the discussion on *Bacillus thurigiensis* subsp. *Kurstaki* were prepared.

Under the follow-up of the actions arising from BPC-14, the Chairman reminded members of the start of the peer review for the renewal of anticoagulant rodenticides and mentioned that the Committee and the applicants will be informed as soon as possible on the day scheduled for the discussion at the BPC meeting in June.

The Chairman stated that, following the input of several BPC members, ECHA is working on the development of guidance for in-situ generated active substances. The preliminary idea is to publish in the coming months a document containing Frequently Asked Questions (FAQ) on the website, taking into consideration the recent questions arriving at the ECHA Helpdesk. In addition, guidance will be developed with the idea to publish a document by the end of the summer.

To follow, the Chairman mentioned that questions have been raised by several MSCAs on the redefinition process under Article 13 of Regulation 1062/2014. This article mentions that the eCA shall inform ECHA after consulting the participant. It was communicated by the Chairman that a proposal on a procedure for this process will be tabled for discussion at the next APCP Working Group.

Actions:

• **SECR:** to upload the agreed minutes from BPC-14 to the BPC CIRCABC IG and to the ECHA website after the meeting.

5. Administrative issues

5.1 Housekeeping issues

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

5.2 Administrative updates and report from other ECHA bodies

The Chairman introduced document BPC-15-2016-01 covering the administrative updates and the report form the other ECHA Committees, provided to members for information purposes. The Chairman noted that the RAC adopted opinions on the harmonised classification for CMIT/MIT, MIT and CMK.

The meeting was also informed that one new ASO that expressed an interest in the work of the BPC: IBMA - International Biocontrol Manufacturers' Association (worldwide association of biocontrol industries producing microorganisms, macro-organisms, semiochemicals and natural pesticides for plant protection and public health). The Committee agreed to accept this organisation as an accredited stakeholder. The list of accredited stakeholders published on the ECHA website will be updated. With regard to the use of R4BP3 in the communication and transmission of documents to applicants, the Chairman mentioned that confidentiality issues may occur in sending the relevant documents to the applicant by the SECR in cases of consortia and/or task forces. In order to avoid this type of issues, the Chairman requested MSCAs to inform the SECR before submitting the draft CAR if a confidentiality agreement was in place between them and the consortium and/or task force.

Actions:

- **SECR:** to update the accredited stakeholders list on the ECHA website.
- **Members**: to provide to SECR confidentiality agreements (if any) in case the participant is a consortium or a task force, before submitting the draft CAR to the SECR.

5.3 Overview of dissemination status of active substances

The Chairman made reference to the overview showing the status of dissemination of the non-confidential assessment reports and non-confidential "Document IIIA" (study summaries) for approved active substances. While the dissemination of the Assessment Report appears to be on track, for many substances "Document IIIA" has not yet been received by SECR. The Chairman reminded MSCAs of sending the non-confidential assessment reports as soon as possible after the adoption of the BPC opinion and urged them to provide the missing "Document IIIA" documents as soon as possible. The Chairman also stated that ECHA will raise this issue at the next CA meeting, as it is not a topic under the remit of the BPC. The Chairman also reminded BPC members that ECHA sent out a communication to MSCAs in the beginning of this year related to the proper redaction of pdf files in order to avoid disclosure of confidential information.

Actions:

• **Members:** to submit to ECHA the remaining non-confidential documents for dissemination.

6. Work Programme for BPC for 2016 – 2017

6.1. Revised Work Programme 2016-2017

The Chairman presented the revised Work Programme, mentioning that this version is a revised version of the previously disseminated one, following consultations with the MSCAs.

The Chairman noted that the current work programme version leads to 50 opinions for the Review Programme, 8 for new active substances and 8 for renewals. The Chairman asked the members to adhere to the planning, as the objective of the BPC is to adopt 50 opinions per year for the Review Programme, and referred especially to the importance of finalising the hypochlorites and chlorine with Italy as eCA.

The Chairman also informed the meeting that ECHA is preparing an overview for the Commission for the next CA meeting on the status of the first priority list indicating:

- the active substance product-type combinations for which the draft CAR was not submitted by the respective eCA by 31 December 2015 and for which the timeline for preparing the BPC opinion could not be started by 31 March 2016;
- the planning of the remaining active substance product-type combinations.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) to the SECR by 21 April 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 for the second priority list

The Chairman referred to the document containing an overview for the substances on the second priority list and pointed out that for 96 active substance product-type combinations a BPC opinion still needs to be adopted. 33 of these are already scheduled for the Working Groups and for the BPC while 49 are not yet scheduled. The Chairman then invited the members to inform the SECR on their planning, especially for those eCAs with a high number of remaining dossiers.

7. Applications for approval of active substances

7.1 a) 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 containing the changes made after the last BPC meeting.

Actions:

• SECR: to revise the document and distribute it via the BPC CIRCABC IG.

7.1 b) Template for BPC opinion

The Chairman introduced the document containing the changes made after the last BPC meeting.

With respect to the statement in section 2.1.a) on assessments under other EU regulatory frameworks it was concluded that these may be added if relevant and that the SECR will be responsible for considering this aspect.

With respect to the assessment of the PBT criteria in section 2.2.1 it was concluded (referring to the discussion on Bardap 26 in BPC-12) that the case of the conclusion "potential P/vP, B/vB or T" refers to situations where there are indications that the substance is meeting one or more of the criteria (for example if the screening criteria are met) but there is insufficient information to come to a definite conclusion. In such a case, additional information under section 2.5 would have to be requested and a discussion in the PBT Expert Group has to take place. If a substance is regarded as "potential P/vP, B/vB or T" this does not imply that it shall be regarded as meeting the exclusion criteria

according to Article 5(1) or as a candidate for substitution according to Article 10. This has to be reflected in the last column of the table in section 2.2.1.

It was concluded that in section 2,3 for condition 3.b the word "possible" has to be removed.

Actions:

• SECR: to inform members on location of templates in CIRCABC and to revise the document and distribute it via CIRCABC.

7.1 d) Active substance renewal

The Chairman made reference to the document which contains for all approved active substances the expiry date and the deadline for the application for renewal. The SECR will also make this document available to the BPC on a regular basis sorted on the submission date for renewal. The Chairman informed that for 2016 one application is foreseen (for creosote in PT 8) and for 2017 two (dichlofluanid and sulfuryl fluoride, both for PT 8). Thereafter the numbers will start to increase. ECHA has started a project on renewal, taken the experience on rodenticides into account and some questions already from one of the members (e.g. when to do a full evaluation and when not). The Chairman informed that the SECR will open a newsgroup on CIRCA after this meeting describing their ideas and questions to be asked to the MSCAs.

Actions:

• SECR: to open a newsgroup in CIRCABC on the topics to be considered for guidance development by ECHA on renewal.

7.1 e) Manual on preparing the draft BPC opinion on an application for approval of an active substance

The Chairman introduced the document containing the changes made after the last BPC meeting.

Actions:

• SECR: to revise the document and distribute it via the BPC CIRCABC IG.

7.2 Draft BPC opinion on CMK for PTs 1, 2, 3, 6, 9 and 13

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

The rapporteur introduced the substance and the general issues related to the assessment report (AR) and opinion were then discussed in detail (modifications are described in the open issues table) PT by PT. The specific points discussed for each PT are summarised below.

The name of the active substance in the Review Programme Regulation¹ and in the harmonised classification entry² and the recently adopted RAC opinion is "chlorocresol". The eCA used the name "p-chloro-m-cresol" in their assessment. These two names are synonyms and refer to the same substance. Even though the name used by the eCA reflects better the chemical structure of the substance, it was agreed that for harmonisation purposes the name "chlorocresol" will be used.

PT 1

The RAC opinion on the classification of the active substance was adopted in March 2016. The BPC discussed the classification of the product. The members supported the eCA's proposal for classifying the product with regard to eye damage as "Eye Dam. 1". However, many members as well as the applicant commented that the classification of the product (containing 4% of the active substance) with regard to skin irritation/corrosion and sensitisation is not justified. A member remarked that currently there is not enough information to understand the assessment and further details should be added to the assessment report. It was also mentioned that discussions on scientific and technical issues should not be re-opened at the BPC. The eCA confirmed that the details of the assessment report. The BPC agreed that the product does not have to be classified with regard to skin corrosion and sensitisation, based on calculations.

Based on the eye effects and agreed classification, a qualitative local risk assessment will be performed by the eCA.

It was clarified that any exposure to the eye during mixing and loading step is accidental therefore the use of goggles in the mixing and loading step is not required. This is valid for PT1 and PT2 and the clarification will be added to the assessment report for both PT 1 and 2.

PT 2

There is an unacceptable risk for general public (with the use of a biocidal product containing 0.1% of the active substance) due to no safe use for children crawling on treated surfaces. Restricting the use to small surfaces was originally suggested by the applicant and considered. It was concluded to add an element in section 2.4 on the risk to children.

PT 3, PT 6 and PT 9

There was a discussion on whether the risk mitigation measures (RMM) should be separated for local and systemic effects. Some members questioned the reason and the possibility for doing that. After some discussion it was agreed that the RMM should be separated for local and systemic effects. This is also a general point to be taken into account for other opinions.

PT 6, PT 9 and PT 13

¹ COMMISSION DELEGATED REGULATION (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council

² Annex VI of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC, and amending Regulation (EC) No 1907/2006

There was a discussion on how to transfer the Tier 2 assessment used in the ART modelling for occupational exposure (low level of containment with 90 % reduction) into practical RMM. This item should be generally discussed in the Working Group Human Health. For CMK only RPE was proposed as RMM.

PT 6

The BPC discussed the need for dietary risk assessment for PT 6. The SECR informed the BPC that the scenarios for food for PT 6 products were discussed at the WG. There are scenarios developed specifically for PT 6 detergents, originally developed for PT4 but according to the guidance they are also applicable for PT 6. The conclusion of the WG was that if there was a risk identified, the assessment can be maintained in the CAR but only for information and transparency reasons and no conclusion can be drawn from that assessment. The eCA performed an exposure assessment and would like to maintain that in the CAR, with adding that the assessment would need to be refined at product authorisation stage. The SECR added that at the WG the reason for not considering the scenarios was that it is very difficult to refine the assessment. In this particular case the eCA pointed out that there are data available from the applicant (for the efficacy of the rinsing step) which could be used at product authorisation stage. The COM highlighted that it is important that the WG agreement is reflected in the BPC opinion.

There was a discussion on the efficacy testing of treated articles referring to an on-going discussion at the Efficacy WG on efficacy of treated articles. It was concluded to remove the requirement from the opinion as the discussions are not yet finalised.

PT 9 and 13

Some clarifications to the assessment reports and opinions were suggested.

All the Assessment Reports were agreed by the BPC, subject to the changes agreed during the meeting. The BPC adopted all the opinions by consensus.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 26 May 2016.**
- **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 5 May 2016** and publish it on the ECHA website.

7.3 Draft BPC opinion on ATMAC/TMAC for PT 8

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

One member state requested a new readily biodegradability study due to the lacking validity of the available studies. This was the result of a bilateral discussion between this MS and the eCA after the Technical Meeting. The Chairman clarified that in any case data requests should be discussed in the working group which had not happened. However, the applicant submitted a position paper to ECHA shortly before the BPC meeting (and not available to the MS) explaining why this study is not considered to be necessary. It was

concluded to include this statement into the assessment report and not to ask for a new study.

The spraying in close tunnel application is not included in the environmental assessment, only for the human exposure assessment. However, there is no release expected to the environment and it was considered to be covered by the dipping scenario. In addition, the chair of the Environment Working group highlighted that there is no ESD for this application.

Regarding the provision related to food and feeding stuff and residue data, to be consistent with similar substances in PT 8 based on the reason that there are only local and no systemic effects, it was agreed that it is not required.

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

Actions:

- **Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 26 May 2016.**
- **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 5 May 2016** and publish it on the ECHA website.

7.4 Draft BPC opinion on calcium oxide / lime / burnt lime / quicklime for PT 2 and 3

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

The Rapporteur introduced the four lime variants – lime, hydrated lime, hydrated dolomitic lime and dolomitic lime – and their uses in PT2 and PT3.

One single open issues discussion table containing all the open issues for the four lime variants was prepared and discussed. The general issues related to the assessment report (AR) and the opinion were discussed first. The specific points discussed are summarised below. Agreed modifications are described in the open issues table.

Assessment report: general comments for all lime variants

The proposal by the eCA to not indicate a cut-off value in the AR was discussed. A member pointed out that in spite of the difficulties to establish a clear cut-off value, a value of 13% of the UL seems to have been used in the assessment by the eCA. Therefore for transparency reasons such value should be indicated together with an explanation on how to use it. The Chairman highlighted that the eCA should check whether the value of 13% is correct.

A member indicated that in addition to the explanation on the WPF value used in the chapter for local effects in the opinion and in the tables 2.3 and 2.4 of AR, it should also be indicated there that WPF stands for workplace protection factor.

The request from a member to have a table summarising the risk characterisation for each scenario included in section 2.2.1.3 was discussed. The proposal by the eCA to instead include the relevant tables of the CAR in Document IIC (with % of AEC and % of AEL) in the Assessment Report was accepted.

The eCA clarified the use of the term 'barrier cream' in the AR but agreed that its use there is not appropriate. A member requested the deletion of the term 'barrier cream' from the opinion and also from Table 2.3 in the AR, since the cream is not a risk mitigation measure (there are no additional protection factors derived from the use of the cream), but just a good occupational practice. Another member requested an explanation to be included in the CAR.

A qualitative assessment on pH changes in surface water indicated to be missing by a member will be addressed by a text proposed by the eCA, provided in advance to the meeting. The member raising the issue indicated to agree with the text provided.

BPC Opinion: general comments for all lime variants

The need to add the WPF value of 40 for RPE in the column "conclusion" of the "Summary table: human health scenarios" for the scenario "Mixing and Loading – automated and manual handling)" was discussed. The eCA agreed to include the WPF value as requested by a member. However the Chairman highlighted that the opinion would in that case become very detailed, and recommended to amend only the AR. As a conclusion the member raising the question agreed to leave the text without amendments.

The need to clarify the paragraph in section 2.1 on local effects was discussed. The eCA proposed an amendment to the text which was accepted by the member raising the issue, but in light of the previous discussion on the term 'barrier cream' it was agreed by that this reference should be removed from the newly proposed text. In addition, another member requested the following to be added to the text: "For inhalation acceptable risk is identified only in automated mixing and loading scenario". This would address their comment on the local risk assessment for the effects on the respiratory tract.

The request to add a conclusion for the application phase in section 2.1 c) systemic effects was accepted by the eCA and the text proposed by the eCA was also accepted by the member raising the issue.

The text to be included in section 2.4, 1, a, was discussed. One Member raised the need to specify that in case of manual bag removal the use would not be safe. The eCA explained that the text included in the opinion is a standard phrase, and for that reason suggested not to change it. The Chairman indicated that in line with the approach taken for other substances, would agree to add a specific element to address the risks related to manual bag removal.

Burnt Dolomitic Lime – BPC Opinion PT 3

A member indicated that their comment on PT 3 also concerns PT 2. The eCA agreed to amend the opinion for PT 2 as well. For all the other comments included in the open issues discussion table, the responses and proposed solutions by the eCA were accepted without further discussion. No further comments were made by the members.

The BPC adopted the opinions on calcium oxide / lime / burnt lime / quicklime for PT 2 and 3 by consensus.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 26 May 2016.**
- **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 5 May 2016** and publish it on the ECHA website.

7.5 Draft BPC opinion on calcium dihydroxide / calcium hydroxide / caustic lime / hydrated lime / slaked lime for PT 2 and 3

The specific points discussed are summarised under agenda item 7.4 above.

The BPC adopted the opinions on calcium dihydroxide / calcium hydroxide / caustic lime / hydrated lime / slaked lime for PT 2 and 3 by consensus.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 26 May 2016.**
- **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 5 May 2016** and publish it on the ECHA website.

7.6 Draft BPC opinions on calcium magnesium tetrahydroxide / calcium magnesium hydroxide / hydrated dolomitic lime for PT 2 and 3

The specific points discussed are summarised under agenda item 7.4 above.

The BPC adopted the opinions on calcium magnesium tetrahydroxide / calcium magnesium hydroxide / hydrated dolomitic lime for PT 2 and 3 by consensus.

Actions:

• **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 26 May 2016.**

- **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 5 May 2016** and publish it on the ECHA website.

7.7 Draft BPC opinion on calcium magnesium oxide / dolomitic lime for PT 2 and 3

The specific points discussed are summarised under agenda item 7.4 above.

The BPC adopted the opinions on calcium magnesium oxide / dolomitic lime for PT 2 and 3 by consensus.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 26 May 2016.**
- **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 5 May 2016** and publish it on the ECHA website.

7.8 A proposal to revise the working procedure

The Chairman introduced the documents prepared by the SECR: i) the revised document containing the proposal from the SECR described in option 2; ii) an example of the "extended" accordance check for the environmental part of the CAR; iii) the timelines for the process flows for the 2017 meetings based on the SECR proposal in option 2. The Chairman thanked one member and COM for their comments and stated that these and the comments made during the discussion at BPC-14 were considered. The Chairman stated that although the SECR is aware of some disadvantages of option 2 compared to option 3, the SECR is proposing this option which was modified to take care of the concerns raised by some members. In addition, the SECR will focus more as mentioned already at the last meeting on the accordance check with the idea to improve the quality of incoming CARs.

The proposal prepared by the SECR was agreed (option 2). Several members stressed the importance of improving the accordance check. This is of high importance especially with respect to the shortened commenting times (35 days instead of 42 days) and the large amount of CARs scheduled for 2016-2017. The Chairman indicated that accordance checklists for all aspects will be prepared by the SECR for discussion at the next Working Group meetings.

Actions:

• **SECR:** to make available the timelines for the revised working procedure after the meeting. To present at the next Working Group meetings the extended accordance checklists.

7.9 Follow-up of second EU Leaching Workshop for wood preservatives

The Chairman introduced the document, the aim of which was to clarify the current situation on open/closed items resulting from the 2nd EU leaching workshop for wood preservatives (June 2013) and to discuss with the BPC the need to take further actions on two remaining open items.

The status of items discussed at the 2^{nd} EU Leaching was presented by the Chair of the ENV WG to the BPC:

- Points agreed during or after the 2nd EU leaching workshop have been added in the TAB (see entry ENV 60), which is uploaded on the ECHA webpage³.
- Open item Protection goals / Acceptability of the current methods to assess the exposure/risk of wood preservatives (PT 8): at WG-III-2015, the majority of WG members concluded that the current methods to assess the exposure/risk of wood preservatives (PT 8) are realistic enough to derive a realistic worst case PEC value for the soil compartment. Therefore, the exposure assessment should remain as it is currently performed and no further refinement is needed (focus of the discussion was on size of the receiving soil compartment and the spatial scale). The item was closed at WG-level with a comment that it can be discussed again depending on reactions from the BPC/CA meeting.
- Open item re-definition of Time scheme: AT WG-I-2014 the WG agreed on the inclusion of a third time point resulting in a re-defined Time-scheme, i.e. Time 1 = 30 days, Time 2 = 365 days and Time 3 = service life. The point was sent to the 57th CA meeting for discussion, where first an impact assessment was requested by the CA meeting. Following the conclusion on the previous point at WG-III-2015, the impact assessment was not initiated so far since the conclusion on the acceptability of the current methods to assess the exposure/risk of wood preservatives was awaited.

With regard to "Protection goals / Acceptability of the current methods to assess the exposure/risk of wood preservatives (PT 8)", the BPC recommended that the definition of protection goals for PT8 will not be taken up now and the exposure and risk assessment methods with regard to the size of the receiving soil compartment and the spatial scale as currently applied are acceptable.

With regard to the re-definition of the Time scheme, some BPC members questioned the need of the impact assessment and asked for immediate application of the new Time scheme. In addition the question was raised if Time 1 (and also the potential new Time 2) is not used for decision making, why are they calculated at all. However, the majority of members was in favour of conducting the impact assessment and an agreement was reached on how to perform it. Based on data collected from MSs (to be taken from Assessment Reports prepared under active substance approval or product authorisation), SECR will perform an impact assessment for the risk assessment at the new TIME2.

The BPC agreed not to use the results based on TIME2 in the decision regarding approval of active substance or authorisation of biocidal products until the impact assessment was

³ Technical Agreements for Biocides (TAB): <u>http://echa.europa.eu/documents/10162/20733977/technical agreements for biocides en.pdf</u>

performed and discussed. One member expressed reservations to this agreement, since it was not within the mandate of the BPC representative to take such a decision.

Actions:

- **Member states:** Start to perform a risk assessment for the new TIME2 (= 365 d), however not using it for decision making (for active substance approval and biocidal product authorisation). Send the risk assessment to SECR via CIRCABC;
- **SECR:** to open a Newsgroup on CIRCABC. To collect the data and perform an impact assessment as soon as sufficient data is available (target: in one year).

7.10 Disseminating the revised Assessment Report following the submission of data after active substance approval

The Chairman introduced the document stating: i) that the document from the Coordination Group on third party dossiers was not yet agreed. However, a revised document taking into account the comments at the last CG meeting was distributed to the BPC members; ii) it was not the attention of the SECR to amend the document already discussed at BPC-8, nor to amalgamate the document from the CG and the one from BPC-8. Instead the SECR prepared a proposal for a procedure on how to take into account new data starting from the submission, to evaluation (peer review needed or not), reporting and dissemination. The Chairman noted that the document still distinguishes between data submitted as requested in the approval (so in section 2.5 of the BPC opinion) and during product authorisation. The Chairman also stated that the case of third party dossiers has been added. Here the text is not fully correct in section 2. What is meant is that the "normal" case would be to use the List of Endpoints not considering the data in the third party dossiers. If not, an Article 75(1)(g) procedure can be initiated by the Commission. As a last resort, an Article 15 procedure can be initiated.

Several more editorial comments were made by the members, which will be incorporated by the SECR. With respect to case 1 (additional data requirements following the peer review process to be submitted to the eCA 6 months before the approval date) it was decided to include always a commenting period with an adequate time for commenting for the members of the BPC. If an endpoint has changed significantly ECHA in consultation with the eCA can decide to discuss the additional data at the relevant Working Group(s) rather than having a commenting period involving the BPC. In addition, the case 'when mistakes and/or calculation errors are identified after the adoption of the BPC opinion', will be added.

With respect to the applicability of the updated list of endpoints (LoEP) at product authorisation it was clarified by the Chairman (referring to a document agreed at the CA meeting entitled "Consideration of cut-off dates for the implementation of paragraph 8(a) of Annex VI of the BPR"; CA-March16-Doc.4.15) that the MSCAs will have to use the most recent published version. This means that for the situations described above, the amended LoEP will have to be used from the point in time this document is made available through CIRCA BC to the MSCAs and to stakeholders via the ECHA web-site. The Chairman indicated that "older" versions of the LoEP will still be available to MSCAs. One member indicated that they will use more critical values in the LoEP, even though the amended version is not yet published.

The Chairman concluded that the document was agreed subject to the incorporation of the comments made. The SECR will amend the document and start using the procedure described in the document.

Actions:

• **SECR:** to revise the document based on comments received and make it available via CIRCABC.

7.11 Revised Assessment Report following the submission of data received after active substance approval:

a) S-methoprene

Following the approval of S-methoprene additional confirmatory data were received by the evaluating Competent Authority (eCA) Ireland to confirm the P status of this active substance. The conclusion of the eCA is that the data show that S-methoprene does not meet the P/vP criterion. One member already commented on the evaluation of the eCA while two other members made comments at the meeting. These latter comments will be sent in writing to the eCA. It was decided to initiate a consultation phase after which ECHA in consultation with the eCA will decide if further discussion is needed at the Environment Working Group.

Actions:

- **Members:** to send comments in writing by 5 May 2016;
- **SECR:** to inform on the outcome of the consultation.

b) Cyproconazole

Following the approval of cyproconazole additional confirmatory data were received by the evaluating Competent Authority (eCA) Ireland on analytical methods. It was decided to initiate a consultation phase after which ECHA in consultation with the eCA will decide if further discussion is needed at the APCP Working Group.

Actions:

- **Members:** to send comments in writing by 5 May 2016;
- **SECR:** to inform on the outcome of the consultation.

8. Any other business

No items were raised.

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 15th meeting of BPC

13-14 April 2016

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 <u>agreed</u> 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-14	
The revised version of the minutes of BPC-14 was <u>agreed</u> as proposed subject to several editorial modifications.	SECR: to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website after the meeting.	
Item 5 – Administrative issues		
5.2 Administrative issues		
	Members: to provide to SECR confidentiality agreements in case the participant is a consortium or a task force, before submitting the draft CAR to the SECR.	
5.3 Overview of dissemination status		
	Members: to submit to ECHA the remaining non-confidential documents for dissemination.	
Item 6 - Work programme for BPC		
6.1. Revised Work Programme 2016-2017		
	Members: to send information on any further changes to the Work Programme (WP) to the SECR by 21 April 2016 .	
	${\rm SECR:}$ on the basis of the changes to update the WP on the ECHA web site and in the BPC CIRCABC IG.	
6.2. Outlook for second priority list		
	Members: to contact SECR on the status of the second priority list substances by 28 April 2016 .	
Item 7 - Applications for approval of active substances		

7.1.a) Catalogue of specific conditions and authorisation stage	elements to be taken into account at the product
	SECR: to revise the document and distribute it via the BPC CIRCABC IG.
7.1.b) Template for BPC opinion	
	SECR: to inform members on location of templates in CIRCABC and to revise the document and distribute it via CIRCABC.
7.1.d) Active substance renewal	
	SECR: to open a newsgroup in CIRCABC on the topics to be considered for guidance development by ECHA on renewal.
7.1.e) Manual/instructions on preparing the active substance	e draft BPC opinion on application for approval of
	SECR: to revise the document and distribute it via CIRCABC.
7.2 Draft BPC opinion on CMK for PT 1, 2,	3, 6, 9 and 13
The BPC adopted by consensus the opinions for the approval of this active substance/PT combination.	Rapporteur: to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR by 26 May 2016.
	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 5 May 2016 and publish it on the ECHA website.
7.3 Draft BPC opinion on ATMAC/TMAC for	or PT 8
The BPC <u>adopted by consensus</u> the opinion 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 26 May 2016.
	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 5 May 2016 and publish it on the ECHA website.
7.4 Draft BPC opinion on calcium oxide/li	ime/burnt lime/quicklime for PT 2 and 3
The BPC <u>adopted by consensus</u> the opinion for the approval of this active substance/PT combination.	Rapporteur: to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR by 26 May 2016.
	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 5 May 2016 and publish it on the ECHA website.	
7.5 Draft BPC opinion on calcium dihydro lime/slaked lime for PT 2 and 3	xide/calcium hydroxide/caustic lime/hydrated	
The BPC <u>adopted by consensus</u> the opinion for the approval of this active substance/PT combination.	Rapporteur: to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR by 26 May 2016.	
	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 5 May 2016 and publish it on the ECHA website.	
7.6 Draft BPC opinion on calcium ma hydroxide/hydrated dolomitic lime for PT 2 a	gnesium tetrahydroxide/calcium magnesium nd 3	
The BPC <u>adopted by consensus</u> the opinion for the approval of this active substance/PT combination.	Rapporteur: to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR by 26 May 2016.	
	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 5 May 2016 and publish it on the ECHA website.	
7.7 Draft BPC opinion on calcium magnesi	Im oxide/dolomitic lime for Pt 2 and 3	
The BPC <u>adopted by consensus</u> the opinion for the approval of this active substance/PT combination.	Rapporteur: to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR by 26 May 2016.	
	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 5 May 2016 and publish it on the ECHA website.	
7.8 A proposal to revise the working proce	dure	
The proposal prepared by the SECR was agreed (option 2).	SECR: to make available the timelines for the revised working procedure after the meeting.	
	To present at the next Working Group meetings the extended accordance checklists.	
7.9 Follow-up of second EU Leaching Workshop for wood preservatives		
The BPC recommended that the definition of protection goals for PT8 will not be taken up now and the exposure and risk assessment methods as currently applied are acceptable.	Members: Start to perform a risk assessment for the new TIME2 (= 365 d), however not using it for decision making. Send the risk assessment to SECR via CIRCABC.	
First an impact assessment is needed for the re- definiton of the TIME scheme (TIME1 = 30 d , TIME2 = 365 d , TIME 3 = service life). An	SECR: to open a Newsgroup on CIRCABC. To collect the data and perform an impact	

agreement was reached how to perform the impact assessment.	assessment as soon as sufficient data is available (target: in one year).
Based on data collected from MSs, SECR will perform an impact assessment for the risk assessment at the new TIME2.	
7.10 Procedure for the submission, evaluatio Report following the submission of data	n and dissemination of the revised Assessment after active substance approval
The document was agreed pending the changes discussed during the meeting.	SECR: to revise the document based on comments received and make it available via CIRCABC.
 7.11 Revised Assessment Report following substance approval: a) S-methoprene b) Cyproconazole 	the submission of data received after active
	Members: to send comments in writing by 5 May 2016.
	SECR: to inform on the outcome of the consultation.

Part III - List of Attendees

Members	European Commission
Applicants	Apologies
BENYKARAOUIDOn WAkzo Nobel Surface Chemistry) for ATMAC/TMAC PT 8	KUSENDILA Christophe (DG SANTE) - via BELEXNDONCKX Raf (CEFIC)
FREEMARITEE Miltra Eiger Barger Bilty Eterrester the the of the second s	CAZELLE Elodie (AISE) Advisers
GRESEARTAGEIR (EPROpean Lime Association – EuLA) for limes PT 2 and 3 COLLETT GORDON Suzanne (NO) STROECH Klaus (Lanxess Deutschland)	BONTEROREAUIBENETBAD (CEPA)
COLLETT GORDON Suzanne (NO)	HUSZAŁ Sylwester (PL)
FOR STIGATISHIC HEARING LANCES DEUTSCHILD	PALOMÄKI Jaana (FI)
DRAGOIU Mihaela-Simona (RO)	RITZ Vera (DE)
GIEXPENts ଧରେ ଅନନ୍ଥାରୀ applicants	STENHOUSE David (UK)
PRULERIER Folder, SEcompanying GRYSPERT Celia, for limes PT 2 and 3 HARRISON John (IE)	Accredited Stakeholder Organisations
JÄGER Stefanie (DE)	HYNES Jarlath (Humane Society International)
JOHN Nina (AT)	SCALIA Mauro (EURATEX)
KOIVISTO Sanna (FI)	
KOMEN Corine (NL)	ECHA Staff
LARSEN Jørgen (DK)	ANTAL Diana
MIKOLASKOVA Denisa (SK)	JANOSSY Judit
VACEK Tomáš	NEGULICI Ligia
ZIGRAND Jeff (LU)	SCHIMMELPFENNIG Heike
ZOUNOS Athanasios (EL)	VAN DE PLASSCHE Erik
Alternate members	
CRESTI Raffaella (IT)	
GAVRIEL Alexandros (CY)	
GÖBLYÖS Dávid (HU)	
ILMARINEN Kaja (EE)	
PYTHON François (CH)	
VANHOUTTE Herlinde	
Invited expert	
HADAM Anna (PL)	

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-15

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-15 meeting

Meeting documents			
Agenda Point	Number	Title	
2	BPC-A-15-2016	Draft agenda	
4	BPC-M-14-2015	Draft minutes from BPC-14	
5.2	BPC-15-2016-01	Administrative issues and repor	t from the other Committees
5.3	BPC-15-2016-25	Overview of dissemination statu substances	us of approved active
6.1	BPC-15-2016-02	BPC updated Work Programme	2016-2017
6.2	BPC-15-2016-03	Outlook for second priority list	
7.1.a)	BPC-15-2016-04	Catalogue of specific conditions and elements to be taken into account at the product authorisation stage	
7.1.b)	BPC-15-2016-05	Revised BPC opinion template	
7.1.c)	BPC-15-2016-06	Revised Assessment Report template	
7.1.d)	BPC-15-2016-26	Active substance renewal	
7.1.e)	BPC-15-2016-27	Manual on preparing the draft BPC opinion on an application for approval of an active substance	
7.8	BPC-15-2016-07	A proposal to revise the working procedure	
7.9	BPC-15-2016-08	Follow-up of second EU Leachin preservatives	g Workshop for wood
7.10	BPC-15-2016-09	Disseminating the revised Assessubmission of data after active	
7.11a)	BPC-15-2016-28	Revised Assessment Report foll received after active substance	
7.11b)	BPC-15-2016-29	Revised Assessment Report following the submission of data received after active substance approval: cyproconazole	
Substance documents			
Agenda Point	Number	Substance-PT	Title
7.2	BPC-15-2016-10A	CMK PT 1	Draft BPC opinion

	BPC-15-2016-10B		Assessment report
	BPC-15-2016-10C		Open issues
7.2	BPC-15-2016-11A		Draft BPC opinion
	BPC-15-2016-11B	CMK PT 2	Assessment report
	BPC-15-2016-10C		Open issues
7.2	BPC-15-2016-12A		Draft BPC opinion
	BPC-15-2016-12B	СМК РТ 3	Assessment report
	BPC-15-2016-10C		Open issues
7.2	BPC-15-2016-13A		Draft BPC opinion
	BPC-15-2016-13B	СМК РТ 6	Assessment report
	BPC-15-2016-10C	-	Open issues
7.2	BPC-15-2016-14A		Draft BPC opinion
	BPC-15-2016-14B	СМК РТ 9	Assessment report
	BPC-15-2016-10C		Open issues
7.2	BPC-15-2016-15A	CMK PT 13	Draft BPC opinion
	BPC-15-2016-15B		Assessment report
	BPC-15-2016-10C		Open issues
7.3	BPC-15-2016-16A		Draft BPC opinion
	BPC-15-2016-16B	ATMAC/TMAC PT 8	Assessment report
	BPC-15-2016-16C		Open issues
7.4	BPC-15-2016-17A	Calcium oxide / lime / burnt	Draft BPC opinion
	BPC-15-2016-17B	lime / quicklime PT 2	Assessment report
	BPC-15-2016-17C		Open issues
7.4	BPC-15-2016-18A	Calcium oxide / lime / burnt	Draft BPC opinion
	BPC-15-2016-18B	lime / quicklime PT 3	Assessment report
	BPC-15-2016-17C		Open issues
7.5	BPC-15-2016-19A	Calcium dihydroxide / calcium hydroxide / caustic lime /	Draft BPC opinion
	BPC-15-2016-19B	hydrated lime / slaked lime	Assessment report
	BPC-15-2016-17C	PT 2	Open issues
7.5	BPC-15-2016-20A	Calcium dihydroxide / calcium hydroxide / caustic lime /	Draft BPC opinion
	BPC-15-2016-20B	hydrated lime / slaked lime	Assessment report
	BPC-15-2016-17C	PT 3	Open issues
7.6	BPC-15-2016-21A	Calcium magnesium tetrahydroxide / calcium	Draft BPC opinion
	BPC-15-2016-21B	hydrated dolomitic lime PT 2	Assessment report
	BPC-15-2016-17C		Open issues
7.6	BPC-15-2016-22A	Calcium magnesium	Draft BPC opinion
	BPC-15-2016-22B	tetrahydroxide / calcium	Assessment report

	BPC-15-2016-17C	magnesium hydroxide / hydrated dolomitic lime PT 3	Open issues
7.7	BPC-15-2016-23A	Calcium magnesium oxide / dolomitic lime PT 2	Draft BPC opinion
	BPC-15-2016-23B		Assessment report
	BPC-15-2016-17C		Open issues
7.7	BPC-15-2016-24A	Calcium magnesium oxide / dolomitic lime PT 3	Draft BPC opinion
	BPC-15-2016-24B		Assessment report
	BPC-15-2016-17C		Open issues



04 April 2016 BPC-A-15-2016_rev1

Final agenda

15th meeting of the Biocidal Products Committee (BPC) 13-14 April 2016

ECHA Conference Centre, Annankatu 18, Helsinki Starts on 13 April at 09:30, ends on 14 April at 16:30

1. - Welcome and apologies

2. - Agreement of the agenda

BPC-A-15-2016 For agreement

3. - Declarations of potential conflicts of interest to agenda items

4. - Agreement of the minutes and review of actions from BPC-14

BPC-M-14-2015 For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other Committees

BPC-15-2016-01 For information

5.3 Overview of dissemination status of active substances

BPC-15-2016-25 *For information*

6. – Work programme for BPC

6.1. Revised BPC Work Programme 2016-2017

BPC-15-2016-02 For information

6.2. Outlook for second priority list

7. – Applications for approval of active substances[§]

7.1. a) Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval (introducing the new wording of the conditions for active substance approval)

BPC-15-2016-04 *For information*

b) Template for BPC opinion

BPC-15-2016-05 For information

c) Template for the Assessment Report

BPC-15-2016-06
For information

d) Active substance renewal

BPC-15-2016-26 For information

e) Manual on preparing the draft BPC opinion on an application for approval of an active substance

BPC-15-2016-27 For information

7.2. Draft BPC opinion on CMK for PTs 1, 2, 3, 6, 9 and 13

Previous discussion(s): WG-V-2015

PT 1: BPC-15-2016-10A, B and C
PT 2: BPC-15-2016-11A, B and BPC-15-2016-10C
PT 3: BPC-15-2016-12A, B and BPC-15-2016-10C
PT 6: BPC-15-2016-13A, B and BPC-15-2016-10C
PT 9: BPC-15-2016-14A, B and BPC-15-2016-10C
PT 13: BPC-15-2016-15A, B and BPC-15-2016-10C

For adoption

[§] 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 which may cover more than one PT (denoted by B) and a document containing open issues covering all the PTs to be discussed for that substance (denoted by C).

7.3. Draft BPC opinion on ATMAC/TMAC for PT 8

Previous discussion(s)TM(ATMAC) WG-II-2015, (ATMAC) BPC

BPC-15-2016-16A, B and C For adoption

7.4. Draft BPC opinion on calcium oxide / lime / burnt lime / quicklime for PT 2 and 3

Previous discussion(s): WG-V-2015

PT 2: BPC-15-2016-17A, B and C PT 3: BPC-15-2016-18A, B and BPC-15-2016-17C *For adoption*

7.5. Draft BPC opinion on calcium dihydroxide / calcium hydroxide / caustic lime / hydrated lime / slaked lime for PT 2 and 3

Previous discussion(s): WG-V-2015

PT 2: BPC-15-2016-19A, B and C **PT 3**: BPC-15-2016-20A, B and BPC-15-2016-17C

For adoption

7.6. Draft BPC opinion on calcium magnesium tetrahydroxide / calcium magnesium hydroxide / hydrated dolomitic lime for PT 2 and 3

Previous discussion(s): WG-V-2015

PT 2: BPC-15-2016-21A, B and C **PT 3**: BPC-15-2016-22A, B and BPC-15-2016-17C

For adoption

7.7. Draft BPC opinion on calcium magnesium oxide / dolomitic lime for PT 2 and 3

Previous discussion(s): WG-V-2015

PT 2: BPC-15-2016-23A, B and C **PT 3**: BPC-15-2016-24A, B and BPC-15-2016-17C

For adoption

7.8. Follow-up on the Workshop "Reviewing the active substance assessment process": a proposal to revise the working procedure

BPC-15-2016-07 For discussion

7.9. Follow-up of second EU Leaching Workshop for wood preservatives

BPC-15-2016-08 *For information*

7.10. Disseminating the revised Assessment Report following the submission of data after active substance approval

BPC-14-2016-09 *For discussion*

- 7.11. Revised Assessment Report following the submission of data received after active substance approval:
 - a) S-methoprene

BPC-15-2016-28 For information

b) Cyproconazole

BPC-15-2016-29 For information

Item 8 – Any other business

Item 9 – Agreement of the action points and conclusions

For agreement



Provisional timeline for the

15th meeting of the Biocidal Products Committee (BPC)

ECHA Conference Centre, Annankatu 18, Helsinki 13 April 2016: starts at 09:30; 14 April 2016: ends at 16:30

Please note that the timings indicated below are provisional and subject to possible change. They are distributed to participants on a preliminary basis.

Wednesday 13 April: morning session

Items 1-5	Opening items and administrative issues
Item 6	Work programme for BPC 2016-17
Item 7.1	 a) Catalogue of specific conditions and elements to be taken into account at the product authorisation stage b) Template for BPC opinion c) Template for the Assessment Report d) Active substance renewal
Item 7.2	e) Manual on preparing the draft BPC opinion on an application for approval of an active substance Draft BPC opinion on CMK for PTs 1, 2, 3, 6, 9 and 13

Wednesday 13 April: afternoon session

Item 7.2 (cont'd) Draft BPC opinion on CMK for PTs 1, 2, 3, 6, 9 and 13

Thursday 14 April: morning session

Item 7.3	Draft BPC opinion on ATMAC/TMAC for PT 8
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- Item 7.4Draft BPC opinion on calcium oxide / lime / burnt lime / quicklime for PT
2 and 3
- Item 7.5Draft BPC opinion on calcium dihydroxide / calcium hydroxide / caustic
lime / hydrated lime / slaked lime for PT 2 and 3

Thursday 14 April: afternoon session

Item 7.6	Draft BPC opinion on calcium magnesium tetrahydroxide / calcium magnesium hydroxide / hydrated dolomitic lime for PT 2 and 3	
Item 7.7	Draft BPC opinion on calcium magnesium oxide / dolomitic lime for PT 2 and 3 $$	
Item 7.8	Follow-up on the Workshop "Reviewing the active substance assessment process": A proposal to revise the working procedure	
Item 7.9	Follow-up of second EU Leaching Workshop for wood preservatives	
Item 7.10	Disseminating the revised Assessment Report following the submission of data after active substance approval	
Item 7.11	Revised Assessment Report following the submission of data received after active substance approval: a) S-methoprene b) cyproconazole	
Item 8	AOB	
Item 9	Agreement of the action points and conclusions	
End of meeting		

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