WG-III-2014

Final minutes

29 September 2014

Minutes of WG-III-2014

2-6 June 2014

Meetings of the Analytical methods and physico-chemical properties, Efficacy, Human Health and Environment Working Groups of the Biocidal Products Committee

Minutes of Analytical methods and physico-chemical properties WG

WG-III-2014 (2 June 2014)

1. Welcome and apologies

The Chair welcomed all participants to the second APCP WG meeting. The list of attendees is given in Annex 1.

2. Agreement of the agenda

The Chair introduced the draft agenda and invited the participants to add any additional items.

- PL requested to include under A.O.B. a question on vapour pressure values.

The agenda was agreed including the proposed item.

3. Declarations of potential conflicts of interest in relation to the agenda

The Chair invited all members to declare any potential conflicts of interest in relation to the agreed agenda. None was declared.

4. Agreement of the draft minutes from WG-II-2014

The minutes from the WG-II-2014 were agreed with minor amendments to the text proposed.

5. Administrative issues

5.1 Housekeeping issues

The Chair gave a presentation on the key aspects of the housekeeping rules including the safety and security rules.

6. Establishment of a reference specification

6.1 Reference source for biocidal active substances under the Biocidal Products Regulation (BPR) (EU) No 528/2012

The Chair presented the document. Following comments on the draft were discussed:

- The statistical analysis $(\bar{X} \pm 3SD)$: It was the opinion of several MS that this calculation should be a help or a tool rather that a rule. Therefore, it should be possible to establish the specification without this calculation.

- Definition of 'Global specification' (previously mentioned in item 4, Agreement of the draft minutes from WG-II-2014).

  "The term global specification also refers to one applicant having the same specification supporting two or more sources of the same active. In such cases a global specification is possible to cover several sources from the same applicant if each has a similar manufacturing process and similar purity/impurity profile"
- In section 2.2. of the document the reference to technical equivalence (TE) tier I should be equally valid for tier II.
- The members of the WG agreed that the document, presented at the WG for agreement, stands alone for terminology. However, some additional information on Toxicology and ecotoxicology should be included. One additional paragraph will be included. FR to provide the text.
- Concerning the inclusion of non-relevant impurities below 0.1% on the specification, it was agreed that this type of impurities can be included in the internal specification, but not in the specification for Union list inclusion.

Conclusions and actions:

Based on discussion held at the working group, the document on '*Specification, Reference specification, Source and Reference source – Terminology used for processes under the BPR*' will be updated by ECHA and distributed to the members of the WG for endorsement (via e-mail) no further discussion is foreseen at the WG meeting. The document will be presented at the BPC meeting for information.

6.2 Approved active substances without reference specification

ECHA informed the members of the WG that the eCAs will be contacted when necessary to get confirmation/clarification on the reference specification and source(s) of the approved a.s.

As explained in the document provided to the WG, the requests and replies will be processed via R4BP 3 as an ad hoc communication and sent to the eCA prior the invoice is paid by the applicant. The forms (Annex I-III) will be attached to the requests and should be completed and returned by the eCA.

MSs commented that under the BPD the 5-batch analysis was not a data requirement and specifications are missing from several dossiers. MSs were also concerned about the 10 day deadline proposed by ECHA to reply to the request.

ECHA proposed to the MSs to send to ECHA the information, if available. For substances where this information would not be available, ECHA proposed to discuss the reference specification at the WG. BPC will be also informed about this procedure.

7. Technical equivalence assessments

7.1 Tebuconazole – DK

The Chair presented the document prepared by the eCA for the assessment of TE and clarified that the request was sent by the applicant before the 1st of September 2013 and

therefore, before the entry into operation of the Biocidal Products Regulation (BPR) (EU) No 528/2012 which poses the obligation of TE on ECHA and not anymore on the MSs. Accordingly the request for Tebuconazole has to be evaluated by the eCA.

Several MS commented on the document. They highlighted that unclear information was provided concerning the size of the batches and the manufacturing site (pilot plant vs. full scale plant). Additionally, further information was requested on the accuracy of the analytical methods.

Conclusions and actions:

The WG agreed that further clarification was needed to reach a conclusion of TE tier I. For tier II, the experts in the other WGs should be consulted.

8. Dry matter calculation

8.1 Method to be used for the calculation of the dry matter

Follow up from previous discussion at WG-II-2014

The following sections of the document prepared by ECHA were discussed by the WG.

- Section 3.1. Where to perform the 5-batch analysis: dry material vs. active substance as manufactured.
- Section 3.2. Preferred calculation method and the pros and cons of each method.
- Section 3.5. Whether the stabiliser should be included in the specification if it is part of the substance.

Conclusions and actions:

The following was agreed: Concerning section 3.1, 5 batch analyses are to be performed on the technical concentration and not on the dry material since the data should reflect what it is actually manufactured. Meanwhile purified material is preferred for determination of the phys-chem properties.

Concerning the preferred method of calculation, as starting point is was agreed that methods 1 or 3 are to be used when no QC data is available. Method 2 is to be used when QC data is available. This should be revised in the future in light of experience. Additionally, UK will provide more clarification on the calculation method 2.

Concerning section 3.5 (solvents and additives), it was agreed that this Section will be re-discussed when data on a real case will be available. It was also concluded that additives if necessary are part of the substance and a change in the additive triggers a technical equivalence assessment. Solvents not needed for stabilisation of the substance should be taken out of the calculation dry matter.

9. Redefinition of substances with regard to SID

9.1 PHMB

The eCA presented the results of the e-consultation. WG further discussed whether based on the information provided (e.g. physico-chemical characteristics and manufacturing

process) these two polymers could be regarded as different active substances. The eCA clarified that data related to the toxicological and ecotoxicological was included for completeness of the comparison.

Conclusions and actions:

The WG concluded that the two sources of PHMB are regarded as two different substances. Then the dossiers should not be merged. For the complete PHMB dossier accordance check will start. For the other dossier of PHMB the evaluation will be on hold until the missing information will be provided.

WG agreed that some criteria need to be defined to differentiate the two PHMB. FR will prepare a document fitting this purpose and for further discussion at the PHMB WG (planned for January 2015).

9.2 Pyrethrin and Chrysanthemum cinerariaefolium extract

The eCA presented the document prepared by a consultancy to support the Applicants position.

Based on the analytical information provided in the document, the WG could not conclude whether the 3 extracts were representative of the same substance. Furthermore, the members of the WG highlighted some issues in the report that would need further clarification such as the pyrethrin ratios, solvent concentration, and manufacturing process.

Conclusions and actions:

The eCA was requested to prepare a supporting document that will be further discussed via e-consultation or at a WG meeting. The document should be drafted following REACH guidance on substance identification and should include the eCA position.

10. Discussion of active substances

10.1 Ampholyt 20 (eCA IE)

Open issues indicated in the discussion table were discussed and agreed by the WG members. Hence the evaluation is agreed by the WG members.

Conclusions and actions:

The eCA to update the CAR based on the conclusions provided in the discussion table.

10.2 MBM (eCA AT)

Open issues indicated in the discussion table were discussed and agreed by the WG members. Hence the evaluation is agreed by the WG members.

Conclusions and actions:

The eCA to update the CAR based on the conclusions provided in the discussion table.

10.3 Propiconazole (eCA FI)

Open issues indicated in the discussion table were discussed and agreed by the WG members. Hence the evaluation is agreed by the WG members.

Conclusions and actions:

The eCA to update the CAR based on the conclusions provided in the discussion table.

10.4 General conclusions

Several general issues where raised during the discussion of the active substances. The conclusions of these discussions are extracted here due to their relevance for future discussion of other active substances under evaluation.

- 5-batch analysis
  The WG agreed that for old 5-batch analysis (i.e. >5 yr), justification is to be provided by the applicant (e.g. quality control data) to support that the data is still representative of the manufacturing process and that the proposed specification still applies.

- Isomeric ratios
  Information on the isomeric ratio needs to be included in the CAR.
  The analytical method of quantification is not to be requested if adequately justified by the applicant, (e.g. based on the manufacturing process)
  However, the analytical method will be requested if a specific isomeric ratio is needed for the active substance to be efficacious.

11. AOB

PL consultation on the value of vapour pressure to be used to define a substance as volatile.

Room document was distributed to the members of the WG. The document will be discussed via a Newsgroup. The members should confirm the correct value (i.e. Pa or KPa).

Minutes of Efficacy WG

WG-III-2014 (3 June 2014)

1. Welcome and apologies

The Chair welcomed all participants to the second Efficacy WG meeting. The members of EFF WG (core, advisors and flexible members) briefly introduced themselves. All core members participated except, Ms Anne Lepage, who had sent her apologies. In addition one alternate member, three flexible members, two advisers and one stakeholder observer participated to the WG-III meeting. The Chair introduced also representatives of ECHA.

Participants were informed that the meeting would be recorded solely for the purposes of writing the minutes and that this recording would be destroyed after the agreement of the minutes. The list of attendees is given in Annex 1.

2. Agreement of the agenda

The Chair introduced the agenda items and invited participants to discuss any additional items at AOB.

Conclusions and actions

No additions to the agenda was proposed and members agreed on the agenda as proposed. All participants agreed on the proposed agenda.

3. Declarations of potential conflicts of interest in relation to the agenda

The Chair invited all members to declare any potential conflict of interest to the agenda items. None were declared.

4. Agreement of the draft minutes from WG-II-2014

SECR introduced one additional sentence in the discussion table for CMIT/MIT proposed by the applicant. This was the only comment received on the minutes from the WG-II-2014. The members agreed on the minutes with the presented addition.

5. Administrative issues

5.1. Housekeeping issues

SECR briefly went through the housekeeping rules of ECHA. The Chair invited all members to alert SECR of any particular difficulties they have experienced.

6. Discussion of active substances[1]

6.1 Ampholyt 20 (eCA IE)

[1] The details of the substance discussions are considered restricted. Only the non-restricted conclusions are reported here.

The need for further information related to efficacious concentrations for the different PTs was discussed. It was concluded that the eCA will be requested to include a more detailed description of the concentration tested and proven efficacious will be included in the CAR.

Members asked about their possibility to check the updated CAR. SECR responded that the Dossier Manager would check that the update is done in agreement with the requests of the WG. In addition the CAR can be checked and commented prior to the BPC in which the active substance is to be discussed. Some Members regarded this procedure not satisfactory.

The WG concluded that the CAR should be updated as specified above. With that amendment the WG agreed on the evaluation of the eCA.

6.2 MBM (eCA AT)

There were no open points concerning efficacy for discussion in the RCOM table, so the discussion table was only provided to record the agreement/disagreement of the WG.

The WG agreed on the evaluation of eCA.

6.3 Propiconazole (eCA FI)

General discussion on efficacy evaluation

Two documents had been submitted prior to the meeting related to principles for evaluating efficacy of active substances. The first document, a discussion paper entitled 'Regulating the use of propiconazole and other PT7 biocides in treated articles' had been submitted by SE. The second paper entitled 'UK Comments on the active substance data requirements in the "Role of Efficacy" paper' was submitted by UK and was circulated as a room document.

SE presented their paper and evaluation of efficacy at the active substance approval stage, in particular when the active is foreseen to be used in treated articles, was briefly discussed. The WG concurred with the views expressed by Sweden that it is not appropriate to defer further evaluation of efficacy to the product authorisation stage if use of the substance in treated articles is foreseen, as no product authorisation will be required.

The WG concluded that as the present guidance 'The role of efficacy in the evaluation of active substances for annex I inclusion' was agreed prior to the BPR, treated articles were not covered by the document. For that reason a revision of the guidance would be justified. A revision was recommended by the WG. The ECHA SECR will explore the procedures for such a revision.

Discussion and conclusion on the CAR

The WG agreed with the eCA that the eCA would re-evaluate the efficacy studies and revise the CAR to show innate activity of propiconazole at the concentrations used in the risk assessment. The importance of showing efficacy at the level used for risk assessment was emphasised. It was also concluded that efficacy of treated articles had not been demonstrated in the assessment, and this should be clear in the CAR.

With the modifications indicated above the WG agreed on the evaluation of the eCA.

7. Technical and guidance related issues

7.1 Efficacy of piperonyl butoxide (PBO) for PT18

The SECR gave an update on the situation with PBO. Following the discussion in the WG-II-2014 meeting as well as further communication with the cCA (Greece) it was decided to start the consultation of the CAR, but to restrict the consultation to the part related to efficacy. The CAR has been uploaded to CIRCABC for comments.

The commenting round will end in time to compile and circulate comments prior to the WG-IV-2014.

Conclusions and actions

Members are encouraged to send their comments on the efficacy part of the CAR according to the timelines given. A discussion to further advice the BPC whether or not PBO is regarded as an active substance is planned for the WG in September 2014.

7.2 Work plan for Efficacy guidance

A presentation concerning the current status and work plan for efficacy guidance was given by SECR. Since the last WG two new guidance documents have been published on ECHA's website: Efficacy Assessment for Product Type 21 Antifouling Products, and Efficacy Assessment for Preservatives.

For three drafts guidance documents on the evaluation of efficacy of disinfectants (PT2), wood preservatives (PT08) and embalming products (PT22) public consultations had finished. The drafts will be revised by relevant Member States.

UK informed that they are hosting a workshop for PT19 in the UK during the autumn of 2014.

Conclusions and actions

ECHA will continue its work on efficacy guidance and update the EFF WG on a regular basis. The WG will also have a role in the preparation of guidance and will endorse guidance before they are published.

7.3 Update of the PT 14 guidance

This guidance deals with the evaluation methodology of efficacy tests for rodenticidal biocidal products. It was endorsed at the CA meeting in 2009 but a need for revision was introduced following disagreements regarding product authorisation in the Coordination Group. The revision has been drafted by NL and was submitted via the Coordination Group/COM to ECHA.

NL briefly introduced the status of the work. Since the last WG the document had been circulated for members of the WG, rodenticide experts and CAs for comments and over 100 comments had been received. The comments had been compiled into groups in a response to comments table and were discussed as follows:

1. Label claims and target species

Several comments concerned claims for other species than house mouse and brown and roof rats. Other comments concerned the need for testing of both of the common rat species due to their difference in bait preference.

Inclusion of voles and field mouse in the guidance was discussed. It was concluded that claims for these species would require species-specific testing due to their different behavioral patterns (also between species of voles). For voles there are products approved under the plant protection products (PPP) legislation, but members thought there would still be a need for biocidal product approvals in particular in case of disease spreading. Vole claims will be restricted to in and around buildings. PPP efficacy requirements for vole claims will be checked. Obviously national regulations concerning protection of species will need to be taken into account.

Also the grey squirrel could be relevant to control in some countries.

It was concluded that the best way forward would be to require species-specific testing and species-specific label claims (for both professional and non-professional products) and that general claims should only be accepted in a few cases.

The claim 'for rats' should only be accepted if both *R. norvegicus* and *R. rattus* had been tested. The guidance will be changed on this point.

For use for rats is sewers, only *R. norvegicus* would need to be tested. However, then the label should specify 'for use in sewers'.

Another acceptable claim would be 'for rats and house mouse'. If that is made testing should include *R. norvegicus*, *R. rattus* and *M. musculus*.

Testing and label claims should be kept at the species level – to specify subspecies would not be realistic.

The **DE expert** will provide a text concerning testing and label claims.

2. Testing, general considerations

Some general comments on testing concerned the delayed effect of rodenticides, if test would be suitable also for voles and other species, the definition of semi-field trials, and the value of different tests. Also the checking of animals during testing was raised. There was also a comment by CEFIC (nr 95) that needed further clarification. **CEFIC** will provide some additional explanations.

The DE expert explained that field trials need to be adjusted depending on the species due to their specific behaviors. Additional information including EPPO test protocol will be provided by the **DE expert**.

Laboratory studies should follow agreed protocols. There are however no existing laboratory strains of voles. It is concluded that also for voles both lab and field studies are required.

DE proposed a change to the paragraph (2.2.1.II) to specify that the important difference between rodenticides is the acute versus delayed action, not the single- versus multi-dose administration. The amendment was accepted.

The semi-field tests were discussed and the **DE expert** offered to provide NL with a definition and a description of the testing (see further 'Waivers' below). It was concluded that well-performed semi-field test were valuable for the assessment of rodenticide efficacy. As animals are housed in groups they are also preferable from an animal welfare viewpoint.

Regarding the higher scientific value of field testing as opposed laboratory testing it was concluded that well-performed laboratory tests may well be of equal or higher scientific

value than field trials as they are well controlled and reproducible. They should preferably be performed on second generation wild animals in groups.

Low numbers of high quality tests are preferred over a high number of tests of low quality. For animal welfare reasons, the number of animals per test should be restricted.

Best methods for checking animals and avoid unnecessary suffering under testing was discussed. It was proposed to include in the guidance that moribund animals should be euthanized. The animals should be checked as often as possible. A paragraph emphasizing that unnecessary suffering must be avoided should be added to the guidance.

NL discussed an additional point that (semi)field tests should be performed using the application rate as mentioned on the label. All agreed that this information should be in the guidance.

3. Testing for damp conditions

Comments here mainly concerned if testing for use in sewers should be done under damp conditions.

The **DE expert** offered to send some descriptions on how the testing of moist bait should be performed. It is not possible according to animal welfare standards to perform the test as such under damp conditions, but the bait should be stored under damp conditions for 5 days prior to testing.

Also the need to test all species claimed in the damp palatability test was discussed, and in principle that should be done. Other species than brown rat would however not be expected to be relevant for sewers, but possibly for other wet environments (e.g. dams).

4. Other test conditions

Comments included comments on Appendix 2.1, 2.2 and 3 describing tests. As the mortality test is not going to be recommended for testing comments on that test are no longer relevant (see further below under 'Waivers').

The level of bait uptake in the bait choice test was discussed. It was concluded that a mortality rate of at least 90% is important, but that the bait consumption per se is of less importance. A lower mortality than 90% should never be accepted (also not for non-bait rodenticides or if other species than rats or house mice are claimed) as that would leave too many animals alive and the population would then grow quickly. If 90% mortality would not be achieved in reality a different method would need to be used, and not a second treatment using the same product.

5. Laboratory studies related to specific efficacy claims regarding storage of the product (section 2.5)

It was concluded that testing of aged bait should always be performed for all claimed species. However, testing would not be necessary for claims not exceeding 24 months as significant changes in palatability or concentration of the active substance would not be expected during the first 2 years.

Accelerated ageing of bait was proposed to be deleted from the guidance as it was considered unlikely that it could simulate longer storage periods than 24 months.

The issue about new regulations for preservatives was raised as that could possibly affect the shelf-life of bait**. CEFIC** offered to provide some information from a WS related to

preservatives. In case of products without preservatives, testing would not be necessary for claims not exceeding 12 months.

6. Testing on resistant rodents

Comments related to resistance concerned testing and identification of resistant strains by genotyping.

The DE expert explained that whilst the understanding of resistance in rat is good, little is known about resistance in mice. There are only a few active substance for which resistance has never been seen. The best way forward is to identify the link between a specific mutation and sensitivity of that specific strain to an active.

UK will send their guidance on resistance to the WG members.

Information about resistant genotypes to the various active substances could be compiled, but such lists would be outdated quickly as more resistant genotypes appear. It is proposed not to authorize any resistance claims anymore. This will also reduce the number of animal experiments. CEFIC will check whether this is acceptable.

The issue about professional and non-professional users and the information need of the latter was raised. It was concluded that non-professional users should be informed that they always need to contact an expert if they fail to get rid of rodents when using rodenticides. Thus, information about resistance to the general public is not meaningful.

7. Waivers

Comments related to waivers included definition of 'comparable bait', questioning the need for mortality testing, and what tests to request in different situation (bait choice, field or semi-field trials).

After some discussion it was concluded that the mortality test gives very little information in addition to data from the bait choice, semi-field and field testing, and could thus be deleted from the testing requirements.

As it is very difficult to define what a 'comparable product ' would be, it was concluded that a field test would always be requested if the composition of a product was changed. Exceptions could possibly include changes of minor importance such as in color of the product. The applicant would if so have to justify why no testing was performed. Members would still prefer to specify in the guidance in which situations the field test could be waived. One possibility would also be to use the efficacy e-consultation group in borderline cases to avoid issues with mutual recognition. Issues with regard to the composition should only be discussed in general terms.

Laboratory testing (bait choice test or semi-field trial) should also be requested for new active substances, or if a product was altered regarding concentration and bait formulation. One exception would be if there were already tests with a fully comparable bait containing an active substance with lower toxicity (if information is available). In such case read-across could be accepted. The **DE expert** promised to provide a list with the toxicity of active substances for different species.

Read-across between species could be acceptable if the applicant could argue that the species were very similar (examples such as common vole and bank vole will be added to the guidance with help of DE expert). Testing of *R.norvegicus*, *R.rattus* and *M. musculus* would however always be requested and no read-across would be possible between those species.

The semi-field test was discussed and it was concluded that it could be used as an alternative both to the field test and the bait choice test. The **DE expert** will provide a description of suitable testing conditions, including animal density.

To minimize lab trials an appropriate testing scheme could be a field test plus a semi-field test **or** a field test plus a bait choice test. In both cases only one lab test would be required.

The figure in appendix 1 will be deleted as it has led to a lot of confusion.

Conclusions and actions

The guidance will be revised to take the comments and discussion in the WG into account. When revised the document will be uploaded to CIRCABC for comments prior to WG-IV-2014. Please see also requests for further information marked in bold in the text above.

8. Any other business

There were no issues for this agenda item.

Minutes of Human Health WG

WG-III-2014 (4-5 June 2014)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 7 core members and 10 flexible members present. There was one accredited stakeholder organisation (ASO) present at the meeting. Applicants were also present for their specific substance discussions.

Participants were informed that the meeting would be recorded solely for the purposes of writing the minutes and that this recording would be destroyed after the agreement of the minutes. The list of attendees is given in Annex 1.

2. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. No additional items to the agenda were proposed. The agenda was agreed without changes.

3. Declarations of potential conflicts of interest in relation to the agenda

The Chair invited all members to declare any potential conflicts of interest in relation to the agreed agenda. None were declared.

The Chair informed the members of an update in the ECHA policy for managing the conflicts of interest, agreed at the March Management Board meeting. There are two consequences for BPC and BPC WG members:

a. There is a new declaration of interest (DoI) template that will replace Annex 2 to the BPC RoPs. The new template should be used when DoIs are updated next year, or if new core members are nominated.

b. The ECHA policy now explicitly states that if members of ECHA bodies have not submitted an annual DoI, they shall not take part in meetings of the ECHA body.

The Chair also informed the members that the first three year term of office started from WG II in March 2014 for human health WG core members.

4. Agreement of the draft minutes from WG-II-2014

The minutes were agreed without further comments, except for the restricted minutes of the active substance CMIT/MIT where minor changes were agreed on.

5. Administrative issues

5.1. Housekeeping issues

The Chair gave a presentation on the key aspects of the housekeeping rules including the safety and security rules.

6. Discussion of active substances[2]

6.1 MBM (eCA AT)

The Working Group members agreed on the evaluation of the evaluating Competent Authority (eCA). The Competent Authority Report (CAR) will be updated based on the agreements. The application proceeds to the Biocidal Products Committee (BPC).

6.2 Propiconazole (eCA FI)

The Working Group members agreed on the evaluation of the eCA. The CAR will be updated based on the agreements. The application proceeds to the BPC.

6.3 Ampholyt 20 (eCA IE)

The Working Group members agreed on the evaluation of the eCA. The CAR will be updated based on the agreements. The application proceeds to the BPC.

6.4 Cholecalciferol (eCA SE)

An early Working Group discussion was held to discuss the acceptability of waiving of some of the core data. The Working Group members agreed with the eCA concluding that waiving is acceptable for the purpose of risk assessment. A further discussion is however necessary at the CA meeting to agree whether further information would be required to establish the applicable BPR provisions.

6.5 PHMB (eCA FR)

FR informed the meeting of the outcome of the discussion in the Working Group on analytical methods and physical-chemical properties. Read-across was considered acceptable between the two substances.

7. Technical and guidance related issues

7.1 Guidance development

The Chair of the *Ad Hoc WG on Human Exposure* gave an update on the group's work. Two recommendations (*Hand disinfection – PT 01 Harmonisation of exposure determinants for professional users* and *Professional Mopping and Wiping Time Used for cleaning Hard Surfaces (PT2)*) were agreed at the TOX Working Group II on 24 March 2014. They were made available on the ECHA website in the webpage dedicated to the Ad Hoc WG on Human Exposure: http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure.

Two recommendations are currently under preparation:

- The model to be used in the refinement of the TNsG 2002 Spraying Model 1 in the assessment of professional exposure to PT18;
- The product application amount for PT19.

Other recommendations are planned to be drafted:

- The hand-to-mouth transfer scenario;

[2] The details of the substance discussions are considered restricted. Only the non-restricted conclusions are reported here.

- The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling;
- The outcome of the ad-hoc follow up of copper pyrithione concerning the scenario of children exposed to copper pyrithione containing products via dermal and oral route.

The Chair informed the members that an Excel file has been uploaded in CIRCABC to inform of the progress in guidance development. The file is available as follows:

Path: /CircaBC/echa/BPC-WG/Library/Non-confidential/09. General information and procedural documents/Guidance related documents

Browse url: https://circabc.europa.eu/w/browse/8f1384c2-dd50-491b-b5a4-1ae00dbbed0e

7.2 Guidance for Human Health Risk Assessment – Volume III, Part B

The Chair informed that ECHA is working on an update of the document, with mostly editorial and formatting changes as the first step. The next step will then be a scientific update of the document, taking into account also the input that could not be included yet because of receiving the input at late stages of drafting the current document. For this update the members may provide text proposals and other suggestions. Any major input should be provided by August and it will be taken into account when ECHA drafts the next version of the document that can then be commented by the MSCAs.

8. Any other business

8.1 Lessons learned

CIRCABC Newsgroups in file transfer

The Chair explained that when the MSCAs need to distribute confidential documents to ECHA or to the WG members, the CIRCABC Newsgroups may be used as a tool for safe file transfer. Any documents uploaded there will be visible to all WG members but they can also be deleted and/or moved to a more appropriate folder within CIRCABC as needed.

Closed/open points in RCOMs

The Chair pointed out the need for the eCAs to pay attention to either closing the points in the RCOM or keeping them open. If the eCA marks a point as open, ECHA will always include them in the discussion table. There have however been several RCOMs where points have been agreed but still marked for discussion with no apparent reason, and this will unnecessarily consume the WG discussion time. The Chair thus urged the eCAs to indicate points as closed whenever they believe that there is an agreement. The exception to this would be the points that are especially important for the risk assessment, such as changes in reference values. Such points should always be agreed by the WG and not bilaterally.

It is important for all MSCAs to check the updated RCOMs because when a point is indicated as closed but another MSCA wishes to discuss this, the point can be re-opened at the request of the MSCA before the discussion table is uploaded in CIRCABC. In practice, such requests should be done within one week after receiving the updated RCOM.

E-mails to SECR

The Chair pointed out that when sending messages to SECR, it is necessary to send a copy to the functional mailboxes:

- For issues related to active substances and the discussion at the WG: biocides-bpc-active-substance@echa.europa.eu
- For issues related to WG organisation, agenda, participation, reimbursement etc: BPC-WGs@echa.europa.eu

This will enable SECR to take action also in the case of absences.

Minutes of Environment WG

WG-III-2014 (5-6 June 2013)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 6 core members present, in addition to 8 flexible members, one adviser and 4 rapporteurs. One accredited stakeholder organisation (ASO) was present at the meeting. Applicants were also present for their specific substance discussions.

Participants were informed that the meeting would be recorded solely for the purposes of writing the minutes and that this recording would be destroyed after the agreement of the minutes. The list of attendees is given in Annex 1.

2. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. The following changes and additional items to the agenda were proposed:

- One point of item 7.2 (i.e. the status of gathering information for the refinement of the ESD for metalworking fluids, PT 13) will be brought forward and presented by a member of the consortium on the first meeting day (the presentation was uploaded after WG-III-2014 to the non-confidential meeting folder on CIRCABC)
- ECHA will provide an updates on ongoing processes relevant for the Environment WG under item 8 (AOB)
- The discussion on items 7.1 and 7.2 will be via WebEx to allow Ad Hoc Environmental Exposure WG members to follow.

3. Declarations of potential conflicts of interest in relation to the agenda

The Chair invited all members to declare any potential conflicts of interest in relation to the agreed agenda. None were declared.

The Chair informed the members of an update in the ECHA policy for managing the conflicts of interest, agreed at the March Management Board meeting. There are two consequences for BPC and BPC WG members:

a. There is a new declaration of interest (DoI) template that will replace Annex 2 to the BPC RoPs. The new template should be used when DoIs are updated next year, or if new core members are nominated.

b. The ECHA policy now explicitly states that if members of ECHA bodies have not submitted an annual DoI, they shall not take part in meetings of the ECHA body.

The Chair also informed the members that the first three year term of office started from WG I in January 2014 for environment WG core members.

4. Agreement of the draft minutes from WG-II-2014

The Chair informed that comments were received from DE, FR, NL, SE and UK and the applicants for dinotefuran and CMIT/MIT which were reflected in the updated minutes.

For CMIT/MIT two points have been clarified and adapted at WG-III-2014, the minutes were then agreed.

Since not comments have been received on the minutes of the other points discussed at WG-II-2014, these have been considered as being agreed.

5. Administrative issues

5.1. Housekeeping issues

The Chair informed that the housekeeping rules including the safety and security rules are not further given as a presentation but in written and are available as a leaflet at the meeting room entrance.

6. Discussion of active substances[3]

6.1 MBM (eCA AT)

The Working Group members agreed on the evaluation of the evaluating Competent Authority (eCA). The eCA can prepare the updated Competent Authority Report (CAR) and proceed to the Biocidal Products Committee (BPC).

6.2 PHMB (eCA FR)

This point was only for information. The eCA provided an update on the outcome of the discussions at the APCP WG.

6.3 Propiconazole (eCA FI)

The Working Group members agreed on the evaluation of the evaluating Competent Authority (eCA). The eCA can prepare the updated Competent Authority Report (CAR) and proceed to the Biocidal Products Committee (BPC). The discussion will take place at BPC meeting in December 2014.

6.4 Cholecalciferol (eCA SE)

The eCA requested an early Working Group discussion in order to clarify the need for additional data. Two points could be clarified but there are still remaining open issues for which an *ad hoc* follow-up was concluded necessary. The results of this ad hoc follow-up were provided on 14 July; since the remaining open point is policy related, it will be forwarded to the CA meeting.

6.5 Ampholyt 20 (eCA IE)

Two points out of ten could not be agreed by the WG. For these points, an *ad hoc* follow-up was concluded necessary. The results of these ad hoc follow-ups were provided on 10 July (No. 2)/ 24 July (No. 1); they will be forwarded to the BPC together with the updated CAR.

[3] The details of the substance discussions are considered restricted. Only the non-restricted conclusions are reported here.

7. Technical and guidance related issues

7.1 Introduction of the Ad Hoc Environmental Exposure WG (ECHA) **– WebEx**

The Chair welcomed the members of the Ad Hoc Environmental Exposure Working Group (Ad Hoc EE WG) who were partly present at the WG meeting and partly attending this agenda item via WebEx. The Chair provided a presentation introducing the Ad Hoc EE WG.

7.2 Update on guidance development (ECHA) **– WebEx**

The Chair presented the status on guidance development. On the guidance on substances of concern it was concluded to that further guidance to cover the environmental part should be continued to be developed.

7.3 Direct emissions to surface waters in PT 6, 7, 8, 9 and 10 (DE)

DE introduced the document which was discussed for the first time at TM-II-2013, followed by a commenting period.

Conclusions and actions

The document was endorsed by the WG members.

The dilution factor of 10 will be kept and potentially revised in the future in the light of further experience. The degradation factor F_{deg} will not be included in the equations for the time being since further guidance on how to derive the factor would be necessary.

7.4 Use scenarios for PT 9 roof membranes (DE)

DE introduced the document which was discussed for the first time at TM-IV-2013.

Conclusions and actions

The document was endorsed by the WG members.

The discussion on the correction of the equations provided in the (revised) OECD ESD for PT8 is also applicable for this document will be send to the Ad Hoc EE WG.

8. Any other business

8.1 Lessons learned from WG-II-2014 (*the presentation was uploaded after WG-III-2014 to the non-confidential meeting folder on CIRCABC*)

The Chair pointed out that when commenting the minutes, if the point was closed during the WG meeting it should not be re-opened during the commenting. When disagreeing with the conclusion of the Working Group and if needed to state the disagreement in the discussion table/minutes, the Member States should request this during the meeting.

The Chair also confirmed that WebEx will not be used for active substance discussions (already indicated at TM IV 2013). Trilateral discussions should always be reported in the updated RCOM and the newsgroups in CIRCACB can be used for safe transfer of files.

As general points, the Chair reminded the members to always include the relevant functional mailbox when sending emails to DMs or the Chair in particular during the WG meeting weeks. In addition, the points that have been closed at the WG meetings should be reflected in the updated CAR.

The WG members provided some feedback to ECHA. In particular some members reported that the discussion tables were very useful, but should be send earlier in order

to prepare to the meeting. The Chair replied that the preparation of the discussion tables is linked time wise to the precedent steps (i.e. trilateral discussions, update of RCOM table) and therefore can only be provided 10 days before the meeting. There was also a request from a flexible member to attach the contact details and prices of the hotels in Helsinki to the invitation in order to facilitate the travel arrangements for the non-reimbursed participants. The Chair confirmed that this will be done for the next relevant WG meeting.

For the questions regarding the use of WebEx, the Chair stated that it could be used for the guidance related discussions in particular for the Ad hoc Environmental Exposure WG.

8.2 General issues for information

The Chair informed the WG members that ECHA is preparing a document for the Biocides CA meeting to clarify on how to proceed with the PBT assessment if the P criteria cannot be assigned (i.e. the substance is "potential P").

In addition, the Chair suggested that as long as EUSES is not updated, it would be helpful to have a website (or CIRCABC site) for PTs where the excel sheets of emission scenarios could be made available and thus all the Member States and the applicants could use the same template. The Chair invited the Member States to provide available Excel Sheets to ECHA. The use of this sheet would be optional and not mandatory.

List of Attendees (Annex 1)

Analytical methods and physico-chemical properties WG

Core members
SIX Therese (FR)
MUEHLE Ulrike (DE)
GATOS Panagiotis (GR)
HUIZING Tjaart-Jan (NL)
CUDMORE Julian (UK)
Alternate core members
WEBER Philippe (FR)
Flexible members
KARHI Kimmo (FI) Rapporteur
KORKOLAINEN Tapio (FI)
CATALDI Lucilla (IT)
HUSZAL Sylvester (PL)
Adviser(s)
THANNER Gerhard (AT)
Stakeholder(s)
MIHAI Camelia (CEFIC)

ECHA Staff
KREBS Bernhard (Chair)
RODRIGUEZ UNAMUNO Virginia
AIRAKSINEN Sanna
LISBOA MARTO Susana
QUINN Bernadette
JANOSSY Judit
SAEZ RIBAS Mónica
Rapporteur
KECK Marianne (AT)
THIERRY-MIEG Morgane (FR)
BROWN Finbar (IE)
TADEO Jose Luis (ES)
SOGORB Miguel (ES)
Applicant(s)
LEONHARDT Wolfgang (Evonik Industries)
HALL Caroline (Evonik Industries)
KLICHE-SPORY Christine (Lanxess Deutschland GmbH)
FALK Uwe (Lubrizol GmbH Germany)
BITSCH Annette (Fraunhofer Institute) - Adviser for FALK
BARLETTA-BERGAN Audrey (GAB Consulting GmbH)
HEINTZE Adolf (GAB Consulting GmbH)

Efficacy WG

Core members
ATTIG Isabelle (FR)
GERRITSEN Lonne (NL)
GIATROPOULOS Athanasios (EL)
KECK Marianne (AT)
HAMEL Darka (HR)
RADU Iuliana (RO)
SIKORSKI Martha (DE)
Alternate core members
GEENEN Petra (NL)
Flexible members
FRANK Ulrike (SE)
KAUKONIEMI Sanna (FI)
HUSZAL Sylwester (PL)
Rapporteurs
KECK Marianne (AT)
KAUKONIEMI Sanna (FI)
Advisers
THANNER Gerhard (AT)
SCHMOLZ Erik (DE)

ECHA Staff
THUVANDER Ann (Chair)
SZYMANKIEWICZ Katarzyna
VAN de PLASSCHE Erik
KREBS Bernhard
SAEZ RIBAS Monica
PECORINI Chiara
JANOSSY Judit
SCHAKIR Yasmin
Applicants
LEONHARDT Wolfgang (Evonik Industries)
HALL Caroline (Evonik Industries)
KLICHE-SPORY Christine (Lanxess Deutschland GmbH)
JAETCH Thomas (Lanxess Deutschland GmbH)
FALK Uwe (Lubrizol GmbH Germany)
BITSCH Annette (Fraunhofer Institute) – expert for FALK

Accredited Stakeholder Organisations
MIHAI Camelia (CEFIC)
Apologies
LEPAGE Anne (BE)

Human Health WG

Core members
BOS Carina (NL)
DE LENTDECKER Chloe (FR)
DE SAINT-JORES Jeremy (FR)
GHITULESCU Rita-Elena (RO)
HOLTHENRICH Dagmar (DE)
NIKOLOPOULOU Dimitra (EL)
RITZ Vera (DE)
Alternate core members
Flexible members
LE DREAU Nina (FR)
SCHMIDT Marianne (DK)
HÄMÄLÄINEN Anna-Maija (FI)
HYVÄRINEN Tuija (FI)
PALOMÄKI Jaana (FI)
HUSZAL Sylwester (PL)

ECHA Staff
AIRAKSINEN Antero (Chair)
ESTEVAN MARTINEZ Carmen
JANOSSY Judit
MYÖHÄNEN Kirsi
PECORINI Chiara
RUGGERI Laura
Accredited Stakeholder Organisations
MIHAI Camelia (CEFIC)
Rapporteur
BERTILSSON Åsa (SE)
PAPARELLA Martin (AT)
REDMOND Aisling (IE)
THIERRY-MIEG Morgane (FR)
KAHRI Kimmo (FI)
Applicants
WRAGG Mick (Lubrizol GmbH Germany)
BITSCH Annette (expert for WRAGG)
LEONHARDT Wolfgang (Evonik Industries)
HALL Caroline (Evonik Industries)
KLICHE-SPORY Christine (Lanxess Deutschland GmbH)
WARREN Simon (Exponent - task force for BASF/Bayer)

Environment WG

Core members
LEFÈBVRE Frederic (BE)
KOIVISTO Sanna (FI)
ALEXANDRE Stéphanie (FR)
CHION Béatrice (FR)
PETERSOHN Eleonora (DE)
OKKERMAN Peter (NL)
Flexible members
PENTTINEN Sari (FI)
AHTING Maren (DE)
FREIN Daniel (DE)
CONROY Kenneth (IE)
CASEY Clare (IE)
NIEBRZYDOWSKA Agnieszka (PL)
COSTA Lenia (PT)
Adviser for Cholecalciferol
PERSSON Johan (SE)

ECHA Staff
SCHIMMELPFENNIG Heike (Chair)
SAEZ RIBAS Monica
BARMAZ Stefania
WIK Anna
Rapporteur
BUCHNER Iris (AT)
KAUKONIEMI Sanna (FI)
THIERRY-MIEG Morgane (FR)
HAHLBECK Edda (SE)
Stakeholder observer
MIHAI Camelia (CEFIC)
Applicants
WRAGG Mick (Lubrizol GmbH)
HAHN Stefan (Fraunhofer)
KLICHE-SPORY Christine (Lanxess)
JAETSCH Thomas (Lanxess)
LEONHARDT Wolfgang (Evonik)
RASCHKA Andreas (EBRC Consulting)
CALLOW Bruce (on behalf of the BASF/Bayer)