WG-I-2017

Final minutes

7 April 2017

Minutes of WG-I-2017

17-25 January 2017

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

Minutes of Analytical methods and physico-chemical properties WG

WG-I-2017 (17 January 2017)

1. Welcome and apologies

The Chair welcomed the participants of the working group meeting. CEFIC was registered as accredited stakeholder organisation (ASO) for this meeting.

Participants of the working group were informed that the meeting is recorded, but solely for the purpose of drafting the minutes and that the recording will be destroyed after the agreement of the minutes. The recording is not released to anybody outside ECHA and any further recording is not allowed.

2. Administrative issue

A presentation on the administrative matters was provided by ECHA for information.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the working group members to include any additional items under any other business.

The following items were added to the agenda:

- ECHA guideline on method validation
- Naming of free radicals

4. 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 by the WG members.

5. Agreement of the draft minutes from WG V 2016

Comments on the draft minutes were received as follows:

Copper: France

ECHA did not agree one comment made by France. Hence, the minutes on the discussion of copper could not be agreed on one topic.

The working group members have agreed to the other parts of the minutes.

6. Follow up of previous working group meetings

6.1 Follow-up of previous Working Groups

ECHA reported that overview tables on open issues have been sent to the eCA as a reminder to follow up on data, which need to be provided by the applicants after the working group meetings. ECHA clarified that additional data is expected at the indicated deadline and the eCA should follow up with the applicant in cases the requested data has not been provided timely. ECHA will update frequently these tables but expects also that the eCA is reporting when the data gap is closed by the applicant.

7. Discussion on the active substances

7.1 Propan-1-ol PT01, 02, 04

All open issues were discussed and agreed by the working group members. The reference specification and reference source have been set but additional information is requested from the applicant.

7.2 Imiprothrin PT18

All open issues were discussed and agreed by the working group members. Additional analytical information is requested. The reference specification and reference source were not set at the meeting but will be followed up by the eCA.

7.3 Cholecalciferol PT14

All open issues were discussed and agreed by the working group members. The reference specification and reference source have been set.

7.4 Icaridin PT19

All open issues were discussed and agreed by the working group members. Additional analytical information is requested. The reference specification and reference source were not set at the meeting but will be followed up by the eCA.

8. Technical and scientific issues

8.1 Peracetic acid "diluted" one or several active substance(s)

A discussion took place whether distilled peracetic acid (non-equilibrium) and peracetic acid in equilibrium (with hydrogen peroxide and acetic acid) which are diluted with water and/or hydrogen peroxide and/or acetic acid should be regarded as new active substance(s) as the concentration of peracetic acid might increase. The working group members agreed that in this case a shift of the equilibrium is not regarded as a new substance because of following reasons:

- Peracetic acid is approved as an equilibrium with acetic acid and hydrogen peroxide.
- A "dilution" would not generate a new substance as the equilibrium is still existent but only shifted.
- The reference specification is based on the compositions of the starting materials (hydrogen peroxide and acetic acid) and not on the concentrations of acetic acid, hydrogen peroxide and peracetic acid in the equilibrium.
- The assessment report of peracetic acid covers a maximum concentration of 15% of peracetic acid. Hence, the concentration of peracetic acid can increase up to 15% in the equilibrium.

However, the working group members did not decide whether the additional generation of peracetic acid should be regarded as manufacture of peracetic acid or

as formulation of peracetic acid (with hydrogen peroxide, acetic acid, water). As this issue is rather regarded as a policy decision than of technical nature. Therefore, it will be forwarded to the coordination group for further consideration and decision.

8.2 DDAC (C_{8-10}), ADBAC (C_{12-14}), ADBAC (C_{12-18}) and ADEBAC (C_{12-14}), early working group discussion

The working groups members agreed with the proposals of the eCA made in the meeting document.

9. Any other Business (AoB)

9.1 Accelerated storage stability

This item was not discussed at the working group meeting but it will be followed-up by e-consultation.

9.2 Hydrogen peroxide reacting with pH-regulator

A brief exchange of opinions took place whether compounds (peroxy acids) generated from hydrogen peroxide and pH-regulators (e.g. organic acids as salicylic acid, glycolic acid) should be regarded as active substances. No conclusions have been taken on this item but the issue might reoccur during product authorisation, hence further discussions or e-consultation, which should also include the efficacy-working group, might be needed in the future.

9.3 ECHA guideline on method validation

The question was raised whether ECHA intends to update the Guidance on the Biocidal Products Regulation, Part A: Information Requirements. ECHA replied that an update is not planned.

9.4 Naming of free radicals

The questions was raised whether radicals generated in situ should be identified by the exact name(s) of the generated radical(s). It was clarified that radicals need not to be specified following the document 'CA-May16-Doc.5.1 – Final'. It is sufficient to identify the radicals as 'free radicals generated in situ from ambient water or air'.

Minutes of Human Health WG

WG-I-2017 (18-19 January 2017)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 20 participants present, of which eight were core members and two alternate core members. Two stakeholder observers were present, one for all agenda items and one for the non-confidential agenda items. Applicants were registered 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. Administrative issues

SECR gave a brief presentation on housekeeping and administrative issues.

The participants should always register to the meeting using the Webropol link provided in the invitation and, in addition, the reimbursed participants should register with the travel agency (CWT). There is no confirmation message sent from the system after the registration. In case of last minute changes (i.e. cancellation), the members should contact the travel agency and SECR immediately.

The rapporteurs are reimbursed only if there are no core members in that WG from the same eCA and if there are still open issues in the discussion table.

The restructuring of Biocides Active Substances IG in S-CIRCABC will start in Q1/2017; the WG members will be informed.

3. 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.

4. 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.

5. Agreement of the draft minutes from WG-IV-2017

The minutes were agreed without changes.

6. Discussion of active substances

6.1 Propan-1-ol (eCA DE) PT 1, 2, 4

There were three open points left that will be closed in an ad hoc follow-up; all concern the derivation of the reference values.

6.2 Imiprothrin (eCA UK) PT 18

There is one remaining open point on deriving an additional reference value. The point will be closed in an ad hoc follow-up.

6.3 Cholecalciferol (eCA SE) PT 14

The discussion points concerned toxicological reference values and human exposure assessment. All points were closed.

6.4 Icaridin (eCA DK) PT19

The WG discussed the relevance to humans of the effects occurring in rats, in addition to reference values and dermal absorption. The derivation of the reference values and the appropriate assessment factors will be concluded in an ad hoc follow-up.

6.5 Silicon dioxides – AEC values (eCA FR)

The eCA had adjusted the AEC values after the agreement during the ad hoc follow-up procedure. The WG members were asked whether they agree with the approach used in the CAR. The members agreed on the eCA approach and the adjustment of the AEC values were confirmed. For silicon dioxide (nano), the DE member did not support the AEC derivation, referring to the minority opinion submitted by DE to the BPC.

7. Technical and guidance related issues

7.1 Update on guidance development

The guidance *Vol V Disinfection by-products* has been finalised and is now available at the ECHA website[1]. SECR gave special thanks to the NL for excellent cooperation in finalising the guidance.

The update of Vol III guidance to address *Part C Assessment* is handled as a corrigendum. The guidance has been finalised and will be published shortly, following a legal check.

The revision of the guidance on technical equivalence has started with a currently open timeline. A new draft will be available during 2017.

SECR will provide the next version of TAB during the first quarter of 2017. Members were requested to send any proposals for TAB entries to SECR in the functional mailbox biocides-bpc-active-substance@echa.europa.eu. SECR also reminded to always copy in at least one member of the SECR in e-mail messages sent to functional mailboxes.

7.2 Update on Ad hoc Working Group – Human Exposure (HEAdhoc)

SECR informed that the twelve recommendations agreed so far by the Working group are publicly available on the ECHA website[2].

The recommendations and projects currently under preparation or consolidation by the HEAdhoc concern the following:

- Revision of HEEG Opinion 17 - Default human factor values for use in exposure assessments for biocidal products, which is under discussion by HEAdhoc members

[1] https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation

[2] https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure

- Spray study in slaughter house for high pressure disinfection, with timelines to be determined
- Validation of excel calculation sheets for human exposure assessment regarding "New scenarios and methodologies" for PTs 3 -5, under commenting until 3 February.

7.2 (a) Recommendation of the Ad hoc Working Group – Human Exposure

Teat disinfection products for veterinary hygiene (PT 3)

SECR introduced the recommendation and the background for developing the document. The aim of the recommendation is to provide harmonised models to assess exposure of professional users to biocidal products for the different tasks occurring during teat disinfection for veterinary hygiene.

For the preparation of this recommendation, the Emission Scenario Document for PT 3 and various HEEG opinions and HEAdhoc recommendations were taken into consideration.

The WG members agreed on the Recommendation, which is now available on the HEAdhoc page of the ECHA website[3].

7.2 (b) Recommendation of the Ad hoc Working Group – Human Exposure

Revision of recommendation 9: Hand disinfection in hospitals by professionals – inhalation and dermal exposure during hand disinfection

The WG member in the lead of the revision of the Recommendation introduced the updates made to the recommendation. The main change in the Recommendation regards the change in the decline curve of concentration in air after the third rub in one room. The decline after the first and second disinfection was not included, but the difference is not significant and does not change the outcome. It was also mentioned that the references to ConsExpo have been updated to ConsExpo Web.

The WG members agreed on the Recommendation, which is now available on the HEAdhoc page of the ECHA website[3], including an Annex with inhalation exposure calculations.

7.3 Update on Ad hoc Working Group – Assessment of residue transfer to food (ARTFood)

SECR informed that the PEG on "Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses" will be launched in February and invited the WG members to take part in the expert group.

7.4 Data requirements for precursors of in situ generated active substances

SECR informed that four main approaches to define the data requirements for precursors of in situ generated active substances were proposed in the input received from members and CEFIC:

1. BPR Annex II as the starting point, with mainly exposure based waiving (suggested by several MSCAs);

[3] https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure

2. Specified data requirements consisting of an acute oral study or appropriate range-finding study, in vitro skin and eye irritation studies, in vitro skin sensitisation study, Ames test, in vitro micronucleus test and a combined repeated dose/repro test (OECD 422) (suggested by UK);
3. BPR Annex III as the starting point, with possibilities of requesting further information based on e.g. the guidance on substances of concern (suggested by SECR);
4. Tiered approach as proposed by CEFIC.

The members were largely in favour of the first approach, considering that the possibility is needed to require information that in some cases would be more than any of the other approaches would easily allow. Such information is needed in order to make a risk assessment for the products where there is no active substance, and where consequently the active substance data set cannot be used. The members considered that the data set for precursors would often be not very complete as many endpoints could be waived based on exposure considerations, read-across, QSARs and weight of evidence. When assessing exposure based waiving, it should be taken into account whether exposure to the precursor takes place also after in situ generation, as in this case exposure to the precursor before in situ generation might be marginal in comparison. The applicants should however provide all information available to them.

SECR reminded that the precursors should be considered as products and therefore, in principle, BPR Annex III should be the starting point. If starting from Annex II, there might be problems related to harmonisation among Member States regarding waiving principles. The SECR also foresaw problems when waiving is accepted for a specific use during active substance approval, but the same waiving would not be acceptable for other relevant uses and such uses might have to be excluded as a consequence of not having the information. The waiving principles in the current guidance are quite strict, and overall, SECR was concerned that having the BPR Annex II as the starting point for data requirements for the precursors could create large problems.

Guidance will be needed for concluding on acceptability of exposure based waiving. This could include triggers or thresholds for concluding that there is "no exposure" or "negligible exposure".

The members agreed that the starting point should be BPR Annex II, while also agreeing that the requirements should be more lenient than for active substances. In practice this should be reached by applying more lenient guidance for waiving than the current BPR guidance. The guidance available in the BPR context was considered too strict, and instead, the guidance under the REACH and PPP frameworks should be considered.

8. Any other business

8.1 Other information & lessons learned

Accordance check

The template/checklist used by ECHA in the accordance check is available in S-CIRCABC with the name *Template extended accordance check*:

- Path: /CircaBC/echa/Biocidal Products Committee (BPC)/Library/Non Confidential Folder/01. Procedural Documents/02. Active substance approval
- https://webgate.ec.europa.eu/echa-scircabc/w/browse/2333a050-9cdd-4514-99e3-f7e59fbfecc2

ECHA will use this from process flow 18, which means using it in the currently ongoing accordance checks.

The eCAs are asked to fill in the checklist from process flow 19, where CARs are submitted by 17 March.

Template for reference value information

SECR reminded of the agreement at WG-V-2016 that the eCAs should provide a document on human health reference values and absorption values together with the updated RCOM (step 15 of working procedure). This document would be provided by filling in Chapters 14.1 *Critical endpoints* and 14.2 *Reference values* of the draft CAR template.

It was agreed at WG-V-2016 that this practice should start from process flow 17, where the deadline for the updated RCOM and the document on reference values is 13 February 2017.

SECR thanked SE for providing this document already for the current meeting.

Public consultation of EFSA dermal absorption guidance

SECR informed that a new draft guidance is available, and a public consultation is ongoing until 24 February 2017 (http://www.efsa.europa.eu/en/press/news/161222). Noting that this guidance is used for biocides, the impact of the revision will require further discussions at the WG at a later stage.

Dermal absorption of anticoagulant rodenticides from formulations

SECR informed that the derivation of reference values has not been progressed because of concerns expressed by COM and CEFIC. The concerns relate to data protection and the ability to use studies submitted in deriving reference values. The SECR will inform the members of any developments.

SECR will clarify the possible ways forward and whether re-evaluated dermal absorption studies of anticoagulant rodenticide active substances and products should be collected in S-CIRCABC.

Combined CAR/CLH template

The template applicable for both CLH and biocides processes was finalised by the task force and is currently being commented by the members of BPC, RAC and CARACAL. Pending on the nature of the comments, the publication is expected to take place in February 2017.

Documents for discussion at WG

SECR reminded the members that any member may suggest an agenda item for discussion at the WG. For such items, the member suggesting the item would normally be expected to provide a document for discussion. Depending on the nature of the item, a commenting period could also take place, possibly followed by a discussion table for the meeting.

Minutes of Efficacy WG

WG-I-2017 (18-19 January 2017)

1. Welcome and apologies

The Chair welcomed all participants to the 15th Efficacy WG meeting. There were 7 core and 2 alternate members who participated in the meeting. In addition, 10 flexible members, one adviser and three ASO representatives (only for the non-confidential agenda items) attended the EFF WG meeting.

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. Administrative issues

SECR gave a brief summary on the administrative issues.

3. Agreement of the agenda

The Chair introduced the agenda items. Members agreed on the proposed agenda.

4. 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.

5. Agreement of the draft minutes from WG-V-2016

The Chair informed that comments for the minutes of WG-V-2016 had been received from DE, concerning the discussion on copper in relation to authorisation of devices and defining the output parameters which have to be met by the devices in order to ensure efficacy of the substance generated *in situ.* The EFF WG amended the minutes on this part, and agreed on the revised version.

6. Discussion of active substances[4]

6.1 Propan-1-ol (eCA DE)

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 EFF WG agreed on the evaluation of the eCA.

6.2 Imiprothrin (eCA UK)

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 EFF WG agreed on the evaluation of the eCA.

The applicant asked during the meeting to re-open the discussion on one of the representative products and informed that a new efficacy study with a lower application rate is ongoing. The eCA was not informed by the applicant before the meeting about such intention. The Chair disagreed to re-open the discussion on

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

imiprothrin and indicated that the EFF WG meeting is not the right place for a such request.

6.3 Cholecalciferol (eCA SE)

There was one open point with three subsections for discussion in the RCOM table. First issue was related to the risk mitigation measure taken in case rodenticide is used in public areas. The EFF WG members pointed out that the EFF WG is not the right body to discuss the risk mitigation measures. Although, it might in general, be wise to inform the general public on ongoing use of rodenticides, the EFF WG decided that from the efficacy point of view it should not be required, at the same time it may be relevant for other purposes.

The second issue concerned resistance management. It was indicated by the EFF WG that this information is relevant for product authorisation stage. As for the time being there is no information on potential resistance and cross-resistance caused by cholecalciferol the EFF WG decided to follow the general approach taken for previously discussed anticoagulants rodenticides and include into the CAR the following sentence: *'Product information of products authorised for the general public against rats and/or mice shall recommend that in case of suspected lack of efficacy by the end of the treatment, the user should contact a pest control service or the supplier of the product'*.

The third issue concerned the phrase *'complete elimination'* proposed to be used in case infested area is treated by a rodenticide. The EFF WG agreed that this phrase is too demanding and after considering several options, i.e. '*sufficient, high level or complete control'* and their possible interpretations it was decided to use word *'control'* instead of *'complete elimination'.*

6.4 Icaridin (eCA DK)

The discussion was reopened by the Chair on request of the NL. NL pointed out that the dose used in HH and ENV risk assessment is not the same as proven by the efficacy tests. The eCA clarified that new efficacy tests to prove the dose used in risk assessment were recently requested and submitted by the applicant. According to these new tests the dose used for HH and ENV risk assessment is efficacious.

In addition DE informed that they intend to commission a comparison laboratory test to arm-in-cage test. Any ideas of the EFF WG members in relation to parameters, species to be used in this test are welcomed. Proposals should be sent to DE including ECHA WG FMB: BPC-WGs@echa.europa.eu.

6.5 Cyphenothrin (eCA EL)

An early EFF WG discussion was initiated by the eCA because of unclear data submitted by the applicant to prove the concentration used for HH and ENV risk assessment. The EFF WG considered this study useful for active substance evaluation, even though it does not support the innate activity of cyphenothrin. The applicant should, however, clarify the application method and the applied dose rate of the product and at product authorisation stage additional data may be required to support efficacy of this biocidal product. The available guidance should also be taken into account. To prove the innate activity of cyphenothrin the applicant provided a protocol and interim study report. The EFF WG considered these new documents acceptable for active substance approval.

6.6 DBNPA (eCA DK)

An early EFF WG discussion was initiated by the eCA as there was no agreement with the applicant on the concentration to be used for the environmental risk assessment. However, the applicant informed that shortly before the EFF WG meeting the whole efficacy package as well as the risk assessment was reviewed internally, and they agree with the eCA. Based on the data and information presented by the eCA and the applicant, the EFF WG agreed on the efficacious concentration to be used in risk assessment for human health and the environment.

7. Technical and guidance related issues

7.1 Update on guidance development

The Guidance Unit gave a brief overview of the ongoing work with efficacy guidance:

- Vol II Assessment+Evaluation (Parts B+C): CA consultation in progress - closing date for comments 20 January 2017. Already published PT specific TGs will be incorporated into Vol II/B+C before publication (i.e. PTs 18+19; PT14; PT1-5; PT21; PT22). Publication is foreseen in February/March 2017.
- Transitional Guidance for PT 14: Published on 13 December 2016, will be incorporated into Vol II B+C (see above).
- Vol II Information requirements (Part A): Commenting launched in December 2016, revision by the EFF WG in progress - no timetable yet for consultation process.
- Vol II/B+C update to PT5: Update planned in 2017 after EFF WG discussion and PEG consultation.
- Vol II/B+C update to PT11/12, and PT19 planned for 2017.

7.2. Appendix 4 of the PT8 efficacy guidance related to Annex A of EN 599-1

FR, supported by EWPM had prepared a presentation based on received comments (28 comments in total) and the revised version of the Appendix 4. All editorial comments had been already accepted by FR. For clarity reasons it was decided to add information that a ready for use formulation refers to the product as marketed, i.e. concentrates (which have to be diluted before application) and ready to use products applied directly without additional dilution step), and that efficacy has to be demonstrated with a concentration during the application. Clarification will be given as well in relation to subsequent authorisations. In section A.2.1 part of the sentence *'Several variations are allowed ('Any or all of the variations')'* will be shortened to *'Any or all of the variations are allowed'*.

In section A.2.2.a the meaning of *'substitution'* (substitution means ~~change or~~ replacement…) and *'chemically equivalent'* will be corrected as well as information requirement related to different function of the ingredients. The last sentence *'Note that […] of the Annex'* was considered misleading and will be deleted.

It was also pointed out that the revision of this document should be coordinated with the upcoming revisions of EN 599-1 and EN 14128.

In section A.2.2.c the first sentence about hazard and risk will be deleted, and only proposed example will remain in the text. Nevertheless, the remaining part of this section needs to be revised, the reference to section A.2.2.b should be deleted, and the value of *'22% total aromatic hydrocarbon solvent'* should be corrected to *'18 to 22%'*.

In section A.2.2.d and e the issue concerning addition of pigments was discussed. It was decided that in case pigment is added the conditions of section A.2.5 should be fulfilled.

Regarding potential impact on the penetration of the product the EFF WG agreed that in case a change of pigment with a higher concentration is made, it should be demonstrated that the penetration of the product is not impacted.

In section A.2.2.h the EFF WG decided to keep the text concerning the concentration change as it is now presented. However, one MS suggested to add examples in order to illustrate what co-formulants are dealt with in this particular sub-section.

In section A.2.3.d, one MS requested to rephrase the information or to delete it.

In section A.2.5 the note related to some substances, which do not reduce the penetration, will be deleted.

A list of available standards demonstrating that penetration is effective will be provided by EWPM.

The date of applicability of this appendix will be consulted by DE at the CA level.

7.3. PT11&PT12 matrix claim

Cefic presented the revised version of the Claims matrix for PTs 11 and 12, and went through the comments received. The main points discussed concerned among others the requirement of growth to show preservation, included in the Vol II/Part B+C. It was brought up by Cefic that the number of microorganisms in a system may increase not only by growth, but also by contamination. DE had proposed to add inoculum density to the matrix, and the EFF WG agreed to include such information of test requirements in the guidance, but not in the claims matrix. The EFF WG discussed whether claims against *Legionella pneumophila* can be made in PT11 or PT12, since they can be regarded as claims to protect humans, which should not be made in main group 2. The EFF WG concluded that since *Legionella* may occur in cooling towers its control should not be restricted to disinfectants. As the division of claims into different PTs is a point with possibly far reaching consequences, ECHA and FR emphasised the claims matrix will be consulted with the CAs.

The selection of test organisms (columns "Min. spectrum of activity" and "Additional optional activity") was discussed. The EFF WG basicly agreed on the propositions from Cefic. However, this will be discussed again when preparing the guidance and decided on at that stage. The need for examples provided in the "Application type", "*Appropriate methodology*" and "*Suggested performance standard…*" columns were also discussed, it was concluded that the column 'Suggested performance standards' needs more consideration, and will therefore be removed from the version to be sent for the CAs. In addition it was agreed that definitions of the terms used in the table will be added to the matrix as a note, but finally will be included in the PT11&12 Guidance document.

FR will send to ECHA the revised version of the matrix by 20 February. In the meantime FR will consult with COM the allocation of borderline claims. The development of the guidance document itself can be discussed in the WG-II-2017.

7.4. Revision of Volume II, Part A – Information requirements

The revision of Volume II, Part A – Information requirements has started based on comments submitted by the EFF WG members. The currently available version was published in 2013 and a minor update was made in November 2014. The content of this document has to be updated, or even developed in some parts to ensure consistency with Volume II, Parts B+C - Assessment+Evaluation. Taking into account all received comments the text of Part A was revised, nevertheless next amendments have to be made. The work was divided between ECHA and the EFF WG members as presented below:

- Preface, Part I (Introduction to the guidance on information requirements), Sections 1.3 till 1.7; 1.9: (ECHA)
- Part I, Section 1.1; 1.2: (NL)
- Part I, Section 1.8: (FR)
- Part II (Dossier requirements for active substances), Sections 6.1 till 6.5 (SE)
- Part II, Section 6.6 (UK)
- Part III (Dossier requirements for biocidal products), Section 6.4 (FR)
- Part III, Section 6.5 (HR)
- Part III, Section 6.6 (SE)
- Part III, Section 6.7 (ECHA)
- Part III, Sub-section 6.8.1 (ECHA)

The updated version of Part A based on first discussion at WG-I-2017 has already been circulated to the relevant EFF WG members, and the revised parts should be sent to ECHA by 14 April 2017, which is not in line with the information given at WG meeting (previously 15 May 2017).

In addition it was agreed that sub-sections 7.1/7.2/7.3/7.4 of Vol I (Identity/physico-chemical properties/analytical methodology), Part A (Information Requirements) will be sent for comments to the EFF WG with the intention to comment on them and then place the revised text Vol II/A.

The updated version (based on our discussion) you can find below:

WGI2017_EFF_7.4_D
raft Guidance Vol_II,

The discussion will be continued in WGIII2017.

7.5. Appendix 4 of the PT1-5 Efficacy Guidance

ECHA presented the revised version of Appendix 4 based on the discussion in WGV2016. The remaining open/unclear points in comments were agreed upon. It was agreed that FR and NL will check footnote 29, and CEFIC will verify the status of prEN 16777 from CEN at the earliest convenience.

The revised version of the Appendix 4 will be published on the BPC EFF WG page:

https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/efficacy

when the last amendments have been finalised.

8. AOB

8.1 Aircraft disinfection - closed session

The EFF WG conclusion of an e-consultation launched 21 March 2016 related to the Aircraft Disinfection was the following: '*Taking into account all received comments the EFF WG considers that for products authorised as insecticides for aircraft disinfection, at least semi-field tests simulating realistic conditions of use (e.g. in unused aircrafts) should be performed*'.

Since the applicant has found this requirement very difficult to meet, the EFF WG was asked to reconsider the decision. UK and DE shared their experiences in evaluating products for aircraft disinsection and described the testing facilities that the applicants in question have used in semi-field trials. There is currently no guideline available that describes a possible set-up for semi-field trials in a laboratory. The semi-field trials in laboratories suggested by applicants (for example to UK) so far have been considered as insufficiently close to a real airplane scenario. Because there is no sufficiently airplane-like laboratory set-up available at the moment, DE suggests to request semi-field trials in airplanes for the time being. However, laboratory trials where airplanes are adequately mimicked should also be allowed in the future, when a guideline with detailed description of such a laboratory set-up might be agreed upon by EFF WG members. BE underlined that applicants should be treated equally, i.e. performing semi-field trial should be mandatory for all applications on aircraft disinsection products already introduced/under review/being introduced in the future, and all applicants should also have equal possibilities to perform testing. A suggestion was made to compile a list of available testing facilities, but ECHA remarked that it is not in the remit of ECHA to compile or maintain such a list due to the prerequisite for independency. It was emphasised that the requirement for semi-field trials concerns only mosquitoes, not other insects. As for the applicant's concern that it might be difficult to transfer mosquitoes to the testing facility the EFF WG concluded that transport of mosquitoes for testing purposes is routinely done and can be easily organised.

Taking into consideration all information presented, the EFF WG agreed with the conclusion suggested by BE and UK to request semi-field tests in line with the WHO guidelines (specific to mosquitoes) simulating realistic conditions of use, using cabin crew training sites or decommissioned aircrafts. If and when a guideline can be established on how to perform semi-field trials within a laboratory setting, these trials will also be considered as sufficient.

8.2 TAB – proposals for inclusion

This agenda item was skipped due to time limitations. ECHA will send written proposals for commenting to the EFF WG members.

8.3 Testing to prove that coformulants are not active

The initial discussion on testing to prove that coformulants are not active substances took place in November 2016 at EFF WGV2016 meeting. The outcome of this discussion indicated that CEN proposal with some modifications suggested by the NL is more supported by the EFF WG members. During commenting period some questions were raised in relation to both options, e.g. respective PTs for identified active substances, organisms tested, setting up the cut-off values or their replacement by dose response data, scientific justification, lg reduction and Tier III etc. The continuation of the previous discussion did not bring any solution, which option is more favourable. As a compromise for the time being it is proposed to give interested parties a choice to start from.

Three kinds of tests have been identified as relevant to demonstrate that an excipient is not an active substance in the product under investigation. These tests are not in a tiered approach, the most appropriate tests for the product and excipient(s) under investigation can be chosen and has to be justified.

1. Test 1) (NL test 2). The product without active substance (formulation only) can be tested at the in use concentration of the product. This should be done in a phase 1 test (most sensitive test organisms, no soiling).
2. Test 2) (WG5 Tier 1). The excipient(s) under question can be tested alone in a phase 1 test (most sensitive test organisms, no soiling). The excipient should

be tested at the concentration in which it is present in the use concentration of the product.

3. Test 3) (WG5 Tier 2, NL test 1). The product without the excipient(s) under question can be tested and compared to the same test with the full product under use concentration. This should be done in a phase 2 step 1 test under worst-case conditions appropriate for the use. The concentration of the active substance should be the same in both tests.

   Further discussion will take place at CEN level end of January 2017.

The EFF WG pointed out that clarification is needed if identified but not notified substances should be considered as active substances. To define a list of of chemicals is not within the EFF WG remit and the decision should be made by regulatory bodies. DE will discuss bilaterally with ECHA how to proceed the request to create a list of chemicals that are potentially active substances.

8.4 PT14: Applications for major changes with lower concentration of an active substance

This agenda item was skipped due to time limitations. ECHA will send written proposal for commenting for the EFF WG.

8.5 Other information and lessons learnt

ECHA informed that accordance check (ACC) template is available in CIRCABC. ACC has to be performed for each CAR submitted by the eCA to verify that the CAR can be proceeded to peer review, for more information please see 'Working procedure for active substance approval'. The eCAs are asked to fill this document in starting from process flow 19 (submission deadline for CARs: 17 March 2017).

Any proposals for discussion at WGII2017 should be sent by 3 February 2017.

The Chair opened the floor for any views, ideas, which could facilitate the preparations for EFF WG meetings. Members called for information when draft minutes are ready for comments and link to the respective 'Newsgroup'. Starting from February 2017 an e-mail will be sent to the EFF WG members including relevant link.

DE informed that a PT19 workshop will be organised in Berlin. Detailed information will be sent soon.

Minutes of Environment WG

WG-I-2017 (24-25 January 2017 and WebEx meeting 27 January 2017)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 19 participants present, of which seven were core members, two alternate members and eight flexible members. In addition one rapporteur and one adviser were present in the meeting. One representative from accredited stakeholder organisation was present for agenda item 7. Applicants were registered 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. Administrative issues

SECR gave a brief presentation on housekeeping and administrative issues.

SECR reminded the participants that the registration to the meeting should always be submitted by using the Webropol link provided in the invitation and, in addition, the reimbursed participants should register with the travel agency (CWT). There is no confirmation message sent from the system after the registration. In case of last minute changes (i.e. cancellation), the members should contact the travel agency and SECR immediately.

SECR also clarified that the rapporteurs are reimbursed only if there are no core members in that WG from the same eCA and if there are still open issues in the discussion table.

SECR further informed the participants that the restructuring of Biocides Active Substances IG in S-CIRCABC will start in Q1/2017.

Finally, SECR indicated that with the exception of WG-II-2017, WG members should reserve the Friday of the WG meeting week for a Webex meeting, in which guidance related items will be covered that could for timing reasons not be discussed at the physical meeting.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the WG members to provide any additional items. The Chair indicated changes in the order of items to be discussed and noted that items 7.2b and 7.5 will be only discussed at the WebEx meeting (scheduled for 27.01.2017). The agenda was agreed.

4. 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.

5. Agreement of the draft minutes from WG-V-2016

The minutes were agreed without further changes.

6. Discussion of active substances

6.1 Propan-1-ol (eCA DE) – PT 1, 3, 4

Two points related to the exposure assessment were discussed. The Working Group members agreed on the evaluation of the eCA. The eCA can prepare the updated CAR and proceed to the Biocidal Products Committee.

Action:

- PT 1: SECR to update **TAB** entry 27 on surgical hand disinfection: the value of 4 was in the meantime agreed by the Ad hoc Working Group on Human Exposure, TAB to be updated: for hand rubs NapplS=4 events/FTE/day (for hand wash with soaps and liquid soaps NapplS will remain 10 events/FTE/day).

6.2 Icaridine (eCA DK) - PT 19

Six points related to effect/hazard assessment and four points related to the exposure assessment were discussed. On point remained open and an **ad hoc follow up** was triggered.

Action:

- eCA to prepare the ad hoc follow up document/SECR to initiate ad hoc follow up.
- SECR to prepare a discussion paper on the use of OECD 308 studies for the risk assessment.
- SECR to prepare an e-consultation to clarify the guidance on AF for PNECwater and the use of additional algae species.
- SECR to perform comparative calculations for sediment compartment if the release via STP covers the swimming scenario.
- SECR to add conclusion on default value for area skin to the **TAB**: the value as proposed in the recommendation of the Ad hoc WG on Human exposure should be used, i.e. 64% of 16600 cm².

6.3 Cholecalciferol (eCA SE) - PT 14

Eleven points related to effect/hazard assessment and ten points related to exposure- and risk assessment were discussed. On point remained open and an **ad hoc follow up** was triggered.

Action:

- eCA to prepare the ad hoc follow up document/SECR to initiate ad hoc follow up.
- SECR to take up the item on the need of and AF if $PNEC_{STP}$ is derived from the water solubility in the frame of the revision of Vol. IV Part B (Infobox 7).
- DE to take up items noted under points 7 and 14 of the discussion table in the revision of the ESD for PT 14.
- SECR to forward minutes on BPC related items to BPC.
- SECR to prepare a request for clarification on the remits of the ENV WG discussions concerning RMM to BPC.

6.4 Imiprothrin (eCA UK) - PT 18

Two points related to effect/hazard assessment and one point related to exposure assessment were discussed. On point remained open and an **ad hoc follow up** was triggered.

Action:

- eCA to prepare the ad hoc follow up document/SECR to initiate ad hoc follow up.

7. Technical and guidance related issues

7.1 Update on guidance development, issues identified for the AHEE (ECHA)

SECR presented the status on guidance development, issues identified for the AHEE and e-consultations. Updates from WG members during the meeting have been included after the WG meeting (see updated table in **Appendix 1** below).

The development of freshwater scenarios (point 1.1) was identified as an item of high urgency. Points 2.20 (area of animal housing) was solved in the frame of the PT 18 EG meeting and point 2.21 (land application interval and manure storage period) was discussed there as well. The outcome of the PT 18 EG meeting will be provided to the ENV WG for agreement. NL volunteered to take over item 2.25 (splitting up releases onsite/off site STP). Point 3.1 will be partly taken up by DE in the frame of the revision of the ESD for PT 14. NL informed that they are at preparing an emission scenario for treatment against tiger mosquitos (e.g. in residential areas) and asked feedback from WG members on already available scenarios on national level. SECR provided feedback on the status of the ESD Excel sheets and on the update procedure (version management: changes compared to previous version to be indicated) and on the finalisation procedure of documents prepared by MS, agreed by the WG.

Actions:

- **SECR** to ask for volunteers for another dedicated expert group meeting on PT 18 (household and professional use) which most likely will take place back to back with WG-III-2017.
- **SECR** to set up newsgroup to collect open items for other PTs than PT 18 in order to prepare an overview on these items.
- **FR, CH, SE, EL** to provide feedback to NL on available scenarios for the treatment against tiger mosquitos on national level (NL to send initial email to MS, SECR in copy).
- **MS** having prepared any document for previous WG meetings, which have been agreed by the WG to provide final versions to SECR to be included in the TAB.
- **MS** requesting to initiate an e-consultation should notify SECR if ASOs can be included in the consultation.

7.2 Agreement of documents discussed at AHEE-1

7.2a Evaluation of the model SimpleTreat (DE)

The ENV WG confirmed the conclusion of AHEE-1 on the document "Application of SimpleTreat version 4.0 instead of current version 3.1 for the environmental exposure assessment of biocides".

The following remaining open items have been further discussed and agreed:

1. *Do you agree that the BOD-Value of 60 g/person/d represents the current situation in Europe and should be set as default in SimpleTreat 4.0 or do you prefer to keep the old value of 54 g/person/d?*

   Conclusion: It was agreed that the new value of 60g/person/d should be set as default value in Simple Treat 4.0.

2. *Do you agree that the SLR of 0.1 kg BOD/kg MLSS/d represents the state of the art in Europe and should be set as default in SimpleTreat 4.0 or do you prefer to keep the old value of 0.15 kg BOD/kg MLSS/d?*

Conclusion: The WG agreed to use a value of 0.1 kg BOD/kg MLSS/d for the sludge loading rate as default value in SimpleTreat 4.0.

3. *Do you agree that the concentration of suspended solids of 7.5 mg/L represents the state of the art in Europe and should be set as default in SimpleTreat 4.0 or do you prefer another value?*

Conclusion: The WG did not agree to the proposed new value of 7.5 mg/L; in the absence of additional information in other countries, the old value of 30 mg/L should be kept.

Action:
- **MS** to provide their sources of information to NL (point 3).
- **SECR** to include the AHEE document and the conclusions in the **TAB**.

7.2b Analysis of regional pleasure craft marina scenarios and proposals for a PEC calculation tool (UK) – WebEx meeting 27/01/2016

The following items have been discussed and agreed:

1.) *Do MS in the Baltic Sea region consider the proposed approach to be reasonable?*

Note that because the Baltic Sea marina database actually includes the existing SE and FI marina scenarios, one advantage of using the exact parameter sets for SE and FI is that results can be compared with existing regulatory modelling frameworks in these MS (see Section 3.1). An alternative approach would be to select either of the parameter sets for the whole region, or use some average parameter set.

Conclusion: The WG agreed that there should be no separation into an Eastern and Western Baltic Sea region, an average value should be rather used. However, no value was defined; the item will be followed up in a short commenting round (including a discussion at the meeting of the Nordic group mid-February). The outcome of the discussion should directly be reported to UK to be included in the document; no further agreement by the WG is needed.

Participants: FI, SE, DK, PL, EE, LT, LV, DE.

2.) *Do MS consider that it would be useful to compare any future regulatory tools or scenarios against existing regulatory scenarios?*

Conclusion: The WG agreed that such a comparison should be performed. The comparison should be part of the further preparation of the Excel tool.

Action: **MS** to provide their existing regulatory scenarios (not noted in the current document) to UK.

3.) *Do MS consider that additional work should be undertaken to compare modelled and monitored concentrations or are they content to progress the work based on the calculated concentrations?*

Conclusion: The WG agreed that for the time being no additional work would need to be undertaken to compare modelled and monitored concentration.

It was noted during the meeting that the discussion monitoring data should be reflected in the minutes: some members (NL, SE) expressed the opinion that the validation of the model with monitoring data would be a lengthy and difficult process, requiring very specific monitoring data. SE highlighted that monitoring data is not required to validate the models currently used for any of the other PT and would therefore be difficult to request if for PT21; nevertheless it could be useful to further refine the exposure values. NL added that the timeframe for the collecting monitoring data does not fit with the timeframe for the conclusion of the model. DE agreed with the previous arguments, adding on the difficulties to assess whether available data is adequate to the model in discussion. DE added that nevertheless monitoring data would be valuable for: 1)

assessing if the model values are of realistic order of magnitude (though given the high uncertainty of the comparison it would be hard to draw conclusions in case the values are not comparable); 2) reassessing outlier results from the model and check the parameterization of the model – marinas for which the model predicts very high or very low PECs, could benefit from monitoring data; according to DE very rough assumptions were made in the model regarding the flow and waterside of the boat, for instance.
SECR agreed with the MS views adding two further points to be considered, based on the experience with an active substances: 1) monitoring data will not differentiate between sources (boats in marinas may have their origin outside Europe) and 2) it should be taken into account that it will take some time before restrictions to uses which are decided now will be reflected in the monitoring data.
FI declared to agree with the views expressed by the other MS.

4.) *Do MS support the further development of substance specific Excel calculation tools?*

Conclusion: The WG supported the further development of substance specific Excel calculations tools.

Volunteers: DK, SE, NL, FR, DE, FI. Step-by-step instruction will be provided by UK (UK to coordinate).

5.) *Do MS agree that a regulatory impact assessment should be performed before agreeing final parameters for use in product authorisation assessments?*

Conclusion: The WG agreed that such an impact assessment should be performed. As a first step, it could be linked to the comparison with existing regulatory scenarios (see Q2). The assessment should be performed in the frame of product authorisation and should be done timewise before the first authorisation is to be granted. Further details of the impact assessment should be defined in the frame of the consultation of risk managers (CA meeting). The CA meeting should also be consulted on the general need of such an assessment.

6.) *Do MS agree that Risk Managers should be consulted over the choice of appropriate percentiles to use for regulatory decision-making?*

Conclusion: The WG agreed that the percentile/level of protection as well as the need for an impact assessment should be forwarded to the CA meeting.

Action: **SECR** to cross check timing on CA meeting discussion with COM. **UK** to prepare a cover paper for discussion at the CA meeting, summarising the discussion item.

Volunteers to support UK: DK, SE, NL, FI, FR, DE.

7.) *Do MS agree that the Excel tool should focus only on losses during service life and that the amended phrasing from the BPC-17 meeting can be included in the product manual to mitigate losses during application, maintenance or repair activities?*

Conclusion: The WG agreed that the Excel tool should focus only on losses during service life and agreed to include the amended phrasing from the BPC meeting in the product manual (mitigation losses).

On the question on percentiles, UK proposed to prepare a short description, which will be followed up in an e-consultation.

Participants: NL, DE, FR, SECR.

Action: **SECR** to initiate e-consultation.

Additional items agreed:

- Reaching a harmonised scenarios on fresh water marinas (core scenarios): lead by NL; interested WG members to contribute: FR, UK, DE, CH. This matter is of high urgency. **Action NL**: To follow up with volunteers.

- **Action SECR**: Question on volunteers (concerning all items in this document) to be send to all WG members.

7.3 Draft ESD for PT 6 (DE)

The WG agreed to the revisions proposed by DE and adopted the draft ESD for PT 6.

Action: **DE** to include the agreed changes in the ESD and provide the final version to SECR for publication on the ECHA ESD webpage.

The main items discussed and agreed are provided in the following:

1.) Section 1.5, Table 3 (Scenario on fuels)

Action: SECR to change priority of this item in the list of open items for the AHEE from low to medium (green to yellow).

2.) Section 3.3. / PT 6.3 - Calculation of emissions from wet-end or other operations (taken over from WGIV2015_ENV_7.2c

Conclusion: The WG agreed that the OECD scenario should be placed in the Annex and the revised scenario which was provided for a specific active substance should be placed in the main text.

3.) Section 3.3.1.4.2 (PT 6.3.1 Paper production, Emission scenario - Application phase)

DE tried to harmonise the notation of the fraction of in-can preservative used ($F_{in\text{-}can}$) throughout the document. However, in some cases they considered it reasonable to stick to other notation, e.g. when factors were not dimensionless.

Conclusion: The WG agreed to the way forward proposed by DE.

4.) Section 1.1, page 31 (CEFIC comment on refinement options)

CEFIC wishes recommendations on refinement options. To DE's understanding, these are general principles not specific for PT 6, therefore DE did not change the text.

The text as provided was agreed. NL indicated to have further comments. It was agreed that if these are editorial, they should be taken into account before providing the final version of the ESD.

Action: **DE** will add further needs for development in a list of items for future revisions as Appendix to the ESD. DE will also add a standard sentence to the ESD that ESD are living documents and that in case where other ESDs are referred to, always the latest version of that referred ESD or related TAB entries should be applied.

5.) Section 3.3.1.4, page 60 (further information for refinements)

DE agreed to add references to existing BREF documents also in other related sections (sub PTs) – **Action DE**.

6.) Section 3.4, page 60 (PT 6.4 Metalworking fluids)

Conclusion: Only a reference to the ESD should be included, no text from the ESD as such.

7.) Section 3.6.4, page 81 (Scenarios for glues and adhesives)

Conclusion: The WG agreed that the scenarios on glues and adhesives should be deleted.

8.) Section 4, page 85 (Cumulative risk assessment and aggregated environmental exposure)

Conclusion: The WG agreed that the text should be deleted; only a reference to the guidance on aggregated exposure under development will be added.

Action: **DE** should transfer the text specific to PT 6 from the ESD to the guidance on aggregated exposure.

9.) Appendix 2.1, page 102 (Table A8)

Conclusion: The WG agreed to delete the given default value for Cform (of 0.001) since this is a set value and no default value is needed.

Action: **NL** will provide further similar editorial comments to DE, to be taken into account by **DE** in the final version.

7.4 AHEE related items, taken up in the disinfection project

7.4a Development of standard surface areas for small-scale RTU products in PTs 2, 3, and 4 (ECHA)

The scenarios prepared in the frame of the disinfection project were presented at WG-IV-2016 (item 7.3, point 5) for information/discussion followed by an e-consultation on the proposed default values for surface areas. The following areas were agreed at the WG meeting:

PT 4 – large scale kitchens: The majority of WG members agreed in the e-consultation to the default surface area for RTUs for PT 4 – large scale kitchens: 50 m². It was agreed to delete the last bullet point in the justification of reasons. No further comment was provided at the WG meeting and the outcome of the e-consultation was confirmed.

PT 4 – slaughterhouses: The majority of WG members agreed in the e-consultation to the default surface area for RTUs for PT 4 – slaughterhouses: 10 m². No further comment was provided at the WG meeting and the outcome of the e-consultation was confirmed.

PT 2 – industrial areas: There was no agreement in the e-consultation on the default surface area for RTUs for PT 2 - industrial areas: 10 m². The following proposals were made:

- In the absence of further information, can the value proposed for large kitchens (i.e. 50 m²) be used as worst case?
- Should the value proposed by FR (25 m²) be used?
- Should the currently agreed provisional value (100 m² = 10% * 1000 m²) provided in the TAB (entry 31, v.1.1) continued to be used?

Conclusion: The WG agreed to use a value of 25 m² (explanation of value provided by FR plus additional comment by DE will be added to the scenario – **Action SECR**)

PT 3 – No scenario needed: There was no agreement in the e-consultation. It was noted that a case-by-case assessment is needed to judge if RTU use needs to be assessed in PT3 depending on the claim of the applicant.

Conclusion: The WG agreed that this should be dealt with on a case by case basis, if further information is available following future applications, a default value could be developed.

Action: SECR to amend the document following the conclusions of the WG and include it in the **TAB**.

7.4b Conversion of surface area to volume when applying the biocidal product by e.g. vaporizing or fogging for PT 2 (ECHA)

The WG agreed to use a value of 4 m for the room height. Taking into account a surface are of 1,000 m^2 according to the ESD for PT 2 (JRC, 2011), the resulting room volume to be considered for vaporizing or fogging in PT 2 is 4000 m^3.

Action: SECR to amend the document following the conclusions of the WG and include it in the **TAB**.

7.5 Refinement of $f_{house}/f_{marketshare}$ (scaling approach) for PT 6.2, 7, 9, 10 (city scenario, roof membranes) (DE/ECHA) - – WebEx meeting 27/01/2016

The WG agreed to the scaling approach proposed by DE, it can be applied for the relevant product types.

Action: **DE** to merge equations 1-3 of the scaling approach into one equation. **SECR** to include the approach in the **TAB**.

7.6 Open items related to exposure assessment in the frame of product authorisation (national/Union) (ECHA)

1.) For Union authorisation, how many of the 9 different EU locations have to show safe scenarios?

The WG concluded that for Union Authorisation all nine scenario should show a safe use.

Action: **SECR** to check with BPC the implications for Union authorisation if not all scenario are safe and to check with ECHA legal department on how to interpret the drinking water directive triggers for biocides.

2.) In case of emission pathways via sewage sludge / manure and other appropriate scenarios: is it necessary to have a set of safe scenarios at the same EU location (i.e. both scenarios, arable land and grassland, should be below the groundwater threshold at the same location)?

The WG concluded that both (arable/grassland) should be acceptable at the same EU location. However if there are specific conditions, case-by-case decisions can be made (e.g. mink stable where only straw is produced, which is to be ploughed into soil i.e. only arable land would be relevant).

Action: SECR to include the conclusions of the WG in the **TAB**.

7.7 PT 3: Emission scenarios for disinfections used in aquaculture (ECHA)

SECR introduced the document. DK noted that there are national uses for the treatment of the water in which the fish are kept, which are so far not covered in the emission scenarios.

It was further discussed that the borderline to veterinary medicine uses needs to be evaluated for these uses.

Action: **SECR** to set up a newsgroup, **MS** to provide feedback on the document in the newsgroup.

7.8 Outcome of e-consultations initiated in Q4 2016 (DE, UK, ECHA)

The relevant MS and SECR provided feedback on the outcome of the e-consultations. In the following only non-active substance related feedback is provided:

PT 18 - Market data for refinement of the exposure assessment (DE). The outcome of the e-consultation was that a refinement of the exposure assessment by using market penetration factors or tonnage data should not be conducted for PT18.

PT 18 - Clarification of areas to be considered for wet cleaning (UK). The outcome of the e-consultation was reported by UK in the meeting and is reflected in the following:

- Use of granules on a carpet: There was general agreement that the assumption of negligible emissions could apply in the case of granules
- Product whose label states that wet cleaning cannot take place following the application of this product: All but 1 of the commenting MS are in agreement that emissions from the wet cleaning of domestic carpets can be considered to be negligible.
- For a product applied to soft furnishings (curtains, bedding, mattresses, upholstered chairs, settees etc.) wet cleaning will not occur so negligible/zero emissions to drains can be assumed: There was general agreement that wet cleaning is not a frequent event to furniture, however it was thought that (unless specifically removed prior to the treatment) bedding and some furniture coverings could be washed leading to emissions.
- Must MS assume that some area of furnishing or carpet will always be subject to wet cleaning after treatment and before a.s. has been removed by continual dry vacuuming/brushing? If so, then what level of wet cleaning must be assumed in the ERA?: one MS proposed to treat the application to soft furnishings, small carpet runners and curtains etc., as a non-wet cleaned surface (with an area of 22 m^2 for a domestic application). In this way, emissions to drain are considered by calculating E_{app}, $E_{mixing/loading}$ and E_{floor}.
- Is there likely to be any significant difference in emissions to drains between a product used in domestic premises (cleaned by homeowners) and products applied in public buildings (cleaned by contracted staff): There is agreement that Yes there are differences in the two situations described above.
- Do MS agree with the above approach and assumptions about total deposition and the potential for wet cleaning? If so, what level of cleaning efficiency should be applied: There is agreement that equation 30 (ESD) does not apply in this case and that 100 % deposition to surfaces could be assumed as a first tier.

  Items on which no agreement was reached in the e-consultation will be taken up in a PT 18 EG meeting on household and professional use (**Action SECR**).

8. AOB

8.1 Other information & lessons learned

SECR reminded on the timelines for the updated RCOM table and (re-)opening items: It is of very high importance that eCAs comply with the submission deadline for the updated RCOM tables (due after the trilateral discussions). All points should have a clear status indicated (open/closed). It is also of very high importance that timelines for re-opening items in the updated RCOM table or opening new additional items are respected (see working procedures step 17/20).

Concerning the sharing of information between ASO and IND, ASO should share information in time with their experts; the discussions with experts from IND should also be channelled via ASOs.

Accordance check template: it is available in S-CIRCABC ("Template extended accordance check").

- Path: /CircaBC/echa/Biocidal Products Committee (BPC)/Library/Non Confidential Folder/01. Procedural Documents/02. Active substance approval
- https://webgate.ec.europa.eu/echa-scircabc/w/browse/2333a050-9cdd-4514-99e3-f7e59fbfecc2

ECHA will use this template from process flow 18 (ongoing accordance checks), the eCAs are asked to fill in the checklist from process flow 19 (submissions by 17 March).

Combined CAR/CLH template: the template should be applicable for both CLH and biocides processes to facilitate the work of MSCAs. MSCAs were invited to join a task force in December 2015, the task force commenting period ended 30 September and was followed by commenting of BPC, RAC and CARACAL. The publication is expected in February 2017.

Mampec 3.1: The release of the new version of MAMPEC v3.1 took place in the 2nd half of October. The complete set of documentation and installation files of version 3.1 available at the website, including an updated version of MAMPEC Handbook v3.1.

Installation files: https://download.deltares.nl/en/download/mampec/ and https://www.deltares.nl/en/software/mampec/#7

Upcoming guidance developments:

- Endocrine disrupters: joint guidance development by ECHA and EFSA and focusses on the interpretation of the Commission criteria. The joint guidance should not include any specifics for either biocides or pesticides. Regulatory consequences should not be included, as these will differ for biocides and pesticides. PEG and MSCA commenting will take place in 2017.
- Technical Equivalence: the work on the update of the guidance will be started in 2017.

The following new documents are available on the ECHA webpage:

- Recommendations for Technical Equivalence Tier II applicants: https://www.echa.europa.eu/web/guest/regulations/biocidal-products-regulation/technical-equivalence
- Procedure for redefinition of an active substance: Review Programme Regulation, Article 13 [Regulation (EU) No 1062/2014]: https://echa.europa.eu/documents/10162/4221979/procedure_redefinition_art_13_en.pdf/37eac4b3-35fc-2f80-9116-202485c97a04

Appendices:

Appendix 1:

Agenda item 7.1: Update on guidance development, issues to be sent to the AHEE

Note:

- Issues unchanged since WG-V-2016 are highlighted in grey shading.
- Closed issues are ~~stroke through~~.

1. Guidance related documents

No.	Title (current leader)	Status
1.1	Scenario for freshwater marinas (**NL**) / PT 21 PA manual (**UK**) **Urgency for freshwater scenarios**	Intention for scenario preparation presented at TM IV 2013. NL has started discussion with IND and has received information from industry. NL has compiled the reactions from the e-consultation on PT 21. **Outcome was included in the PT 21 PA manual discussed at AHEE-1. Endorsement scheduled for WG-I-2017.**
1.2	Leaching to groundwater from paint, coatings and plaster (**NL**)	The document was discussed at WG-II-2015. NL agreed to make some clarifications in the document for better readability. The document was distributed for commenting after WG-II-2015, no comments have been received (commenting period ended on 8/5/2015). DE commented directly to NL during the physical meeting. **The document will be updated and NL will explain the method in more detail**.
~~1.3~~	~~Proposals for standard scenarios and parameter setting of the FOCUS groundwater scenarios when used in biocide exposure assessments (**DE**)~~	~~Discussed at WG-II-2014: two remaining open issues have been identified: a) the application date for manure application on grassland as well as b) the application method and soil depth for manure application on grassland (5 cm incorporation or surface application).~~ ~~**Discussion at AHEE-1, endorsement at WG-V-2016. The document will be included in the TAB 1.3.**~~
1.4	Evaluation of the model SimpleTreat (**DE**)	DE did not yet receive the final report and the announced manual for the new SimpleTreat version. DE is currently clarifying some open points with the provider of the tool; the final report will be provided to WG members as soon as these are solved. A document was provided for information at WG-I-2016. **Discussion at AHEE-1, endorsement scheduled for WG-I-2017.**
~~1.5~~	~~Environment Substances of Concern (SoC) (**DE/DK**)~~	~~At WG-III-2014 it was concluded that further guidance to cover the environmental part should be continued to be developed.~~

No.	Title (current leader)	Status
		~~DE prepared a proposal based on the work done so far by UK and included comments from the former SoC WG, which was send to DK for a first commenting. DE included comments from DK into the guidance.~~ ~~Endorsement by written procedure was initiated on 10 June with a deadline for commenting until 29 July, comments were provided from FR, NL, UK, CH. DE provided an updated version together with an RCOM table on 25 August 2016.~~ ~~**SECR included the revised version prepared by DE in Vol. IV Part B (biocidal product), to be further processed by the PEG.**~~
1.6	2nd EU Leaching Workshop for PT 8 (**ECHA**)	*Reminder:* ***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. ***SECR*** opened a Newsgroup on CIRCABC[5] in order to collect the data and perform an impact assessment as soon as sufficient data is available (target: in one year). **SECR** to include additional time also in the Excel sheet for PT 8 currently under preparation.
1.7	Fish net scenario (**ECHA**): discussion on the usefulness of the new version of MAMPEC to be initiated	Discussion was started by NO. **Possible inclusion in MAMPEC discussed with Deltares at AHEE-1, funding to be clarified by SECR (=> most likely in 2017)**.
1.8	1st revision of Vol. IV Part B (active substance) + new biocidal product part including SoC) (**ECHA**)	1st revision: definition of subjects for first revision and assignment of volunteers taking over the subjects were agreed at WG-I-2016, revised text parts have been provided by 15 June 2016. After discussion of some items at WG-IV-2016. The PEG consultation was initiated in December 2016. **Discussion of the revised text will take place in the frame of the PEG. PEG meeting scheduled on 16 March 2017.**
1.9	Guidance on aggregated exposure assessment (**DE**)	The discussion of the draft guidance is re-scheduled for an electronic procedure, **to be started in Q1 2017**.
1.10	TAB (**ECHA**): Technical Agreements on Biocides	The second revision of the TAB was finalised, containing now also APCP items (TOX and ENV unchanged). The next revision resulting in version 1.3 contains revised TOX and ENV entries and will be distributed end of February 2017 for a six week commenting period.
1.11	ESD for PT 6 (**DE**)	DE has revised the ESD following comments received. **The ESD will be discussed/endorsed at WG-I-2017.**
~~1.12~~	~~Guidance on disinfectant by-products (Dedicated WG)~~	~~The PEG written consultation is concluded, the CA consultation is planned to be launched on 19 September (4 weeks for commenting).~~ ~~**Publication foreseen in December 2016.**~~

[5] **Path:** /CircaBC/echa/BPC-WG/Newsgroups/ENV WG Impact assessment for PT 8 - new TIME scheme
Browse url: https://webgate.ec.europa.eu/echa-scircabc/w/browse/97974dd4-2b7c-411b-99c1-9f8de5090990

No.	Title (current leader)	Status
1.13	Evaluation of ESD PT 14	Shortcomings of the current emission scenario document for rodenticides (ESD PT14) became obvious within the national product authorisation of rodenticides. UBA Germany has initiated a research project to review the described scenarios and assumptions. The project is scheduled from January 2016 to November 2017.

2. Issues identified for the AHEE (related to exposure assessment)

No.	Title (current leader)	Status
ASSIGEND ITEMS		
2.1	How to use market share data in order to derive a market penetration factor different from default values? ⇨ *WG-I-2015 – item 6.2 + WG-II-2015 – item 7.3 WG-II-2014 – item 6.4 (pulp and paper processing fluids)*	AHEE consultation ended on 28 August 2015. Based on the comments received the proposal will be revised and then re-commented/confirmed by AHEE. A discussion of specific items took place at WG-IV-2015 and at AHEE-1. **One item (collection of tonnage data) was discussed at BPC-17. Revised recommendation will be send to AHEE in Q1 for commenting, endorsement of revised recommendation by ENV WG scheduled for WG-II-2017.**
2.2	PT 2, 3, 4: Preparation of specific scenarios for RTU - small scale applications ⇨ *WG-III-2015 – item 7.3*	ECHA contracted out the preparation of scenarios. **Following the e-consultation post WG-IV-2016, the proposed amendments will be discussed at WG-I-2017.**
2.3	PT 18: Development of equations to take into account degradation in manure ⇨ *WG-V-2015 – item 7.2b*	NL volunteered to take over this point. **Discussion at AHEE-1, endorsement at WG-V-2016. Several members will provide further comments on minor issues directly to NL. Document will be included in TAB 1.3.**
2.4	Clarification on DT50 values according to the FOCUS guidance to be used for modelling purpose and as trigger value (for higher tier studies/PBT assessment) ⇨ *WG-I-2016 – item 6.3b*	**DE/UK** volunteered to take over the item (update of PBT guidance to be taken into account). Timing to be defined.
2.5	Proposal on exposure assessment of metabolites in the terrestrial compartment ⇨ *WG-II-2016 – item 6.4*	DE will prepare a proposal for discussion. Discussion at AHEE-1 and WG-V-2016. **An e-consultation was initiated after the WG meeting to close points 3 to 7. If the results of the consultation is unambiguous, the document will be endorsed in a written procedure. If not, the item will be re-discussed at WG-II-2017.**
2.6	PT 2: Conversion of surface area to volume when applying the b.p. by e.g. vaporizing or fogging	ECHA contracted out the preparation of a first proposal. **Item scheduled for endorsement at WG-I-2017.**

No.	Title (current leader)	Status
	⇨ *WG-IV-2016 – item 7.3*	
2.7	PT 3: Scenario for disinfection in aquaculture ⇨ *Disinfection project/EMA visit*	ECHA contracted out the preparation of a first proposal. **First discussion scheduled at WG-I-2017.**
2.8	PT 21: How to use data on background concentrations in the env. risk assessment ⇒ *WG-IV-2015 – item 6.3 (reference below the DTs to the respective RCOM table entries)*	FR volunteered to take over the item. Timing to be defined.
2.9	PT 11: Which fraction should be used to calculate the PEC in soil following deposition from air? ⇨ *WG-IV-2016 – item 6.3*	NL volunteered to take over the item. Timing to be defined.
OPEN ITEMS (priority indicated in colours: high = red, yellow = medium, green = low; prioritisation based on the time lines provided in Annex III of the RPR)		
2.10	PT 18: How to derive values for the cleaning efficiency FCE (=> Release and exposure estimation of the biocidal product during cleaning step) ⇒ *WG-III-2015 – item 6.4*	AHEE member to take over item to be assigned.
2.11	PT 8: Use of a standard transfer factor (38 or 40) for transferring an application rate per volume to an application rate per surface (leaching rate assuming 100% leaching) or use of a specific transfer factor based on the dimensions of wooden commodity per scenario (of OECD ESD PT 8). ⇒ *WG-IV-2015 – item 6.2*	AHEE member to take over item to be assigned.
2.12	PT 6: Development of an emission scenario for the preservation of unrefined fuels ⇒ *WG-V-2015 – item 7.3*	AHEE member to take over item to be assigned
2.13	Development of RTU/small scale application scenario for PT 18 (household and professional use) ⇒ *WG-II-2016 – item 6.2*	AHEE member to take over item to be assigned.
2.14	Development of a proposal on how to use Fsim in an aggregated exposure assessment for PT 18 ⇒ *WG-II-2016 – item 6.2*	AHEE member to take over item to be assigned.
2.15	Refinement options for PT 11 once through and large recirculating systems	AHEE member to take over item to be assigned – document form industry awaited.

No.	Title (current leader)	Status
	⇒ *WG-II-2016 – item 6.8/6.9*	
2.16	PT 21: AHEE consultation - consideration of the PT8 ESD for accumulation and degradation processes (equation 3.11), and the emission pattern for soil exposure (batch-wise vs. continuous release). ⇨ *WG-III-2016 – item 6.4 (AHF)*	SECR to initiate.
2.17	PT 8: Proposal for emission scenarios on how to assess short term antisapstain treatments *WG-III-2016 – item 6.7/BPC-17*	AHEE member to take over item to be assigned.
2.18	PT 7: Revision of the ESD (inclusion of the formulation step, alignment of equations with A/B tables) ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.19	PT 9: Definition/revision of fixation factors for PT 9 – leather applications ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.20	PT 18: Area of animal housing to be considered for applications in PT 18 ⇨ *WG-IV-2016 – item 7.3*	Solved by the PT 18 EG meeting.
2.21	PT 18: Land application interval and manure storage period in PT 18 ⇨ *WG-IV-2016 – item 7.3*	Discussed in the frame of the PT 18 EG meeting.
2.22	PT 10: Removal processes ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.23	PT 9: Concentration in soil in PT 9 rubber-roof membrane scenario ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.24	Focus SWASH: Use of the model for calculation of PEC in sediment (PT 3, run-off from soil) ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.25	PT 4: Is splitting up the release from on-site/off-site STP in the case of large breweries relevant and is the proposed percentage (on-site = 33% / off-site = 67%) realistic?	NL volunteered to take over the item.

No.	Title (current leader)	Status
	⇨ *WG-V-2016 – item 6.1*	

1. ENV WG e-consultations on items that came up during product authorisation/mutual recognition or AS evaluation

Agreed procedure for items that came up during product authorisation at WG-V-2016: the CA who initiated the e-consultation on a specific item should prepare the summary and conclusion of the consultation which will then be presented by the CA at the subsequent WG meeting for information (not for re-discussion or agreement). If relevant, it will be noted in the minutes of the respective WG meeting if the conclusion should be reflected in the TAB or if further actions are required.

No.	Title (current leader)	Status
3.1	PT 18: Consultation on ESD PT 18 (household + professional uses) - bait box scenarios (**NL**)	Questions raised by NL in the frame of MR, consultation initiated on 15 September 2016. Comments have been received from DE and FR. **Questions were included to item 7.3 of WG-V-2016, will be partly taken up by DE in the revision of the ESD for PT 14 (tbc).**
3.2	PT 18: Clarification of areas to be considered for wet cleaning (**UK**)	Deadline for commenting was 21 October 2016, comments have been received from CH, FR, DE, PL, DK. **UK will report outcome at WG-I-2017**
3.3	PT 4: New emission scenarios for DBNPA (**DK**)	Deadline for commenting was 4 November 2016, comments have been provided by NL, DE, FR, UK. **DK will report outcome at WG-II-2017**
3.4	PT 18: Market data for refinement of the exposure assessment (**DE**)	Deadline for commenting is 30 November 2016. **DE will report outcome at WG-I-2017**
3.5	PT 18: Aircraft disinsection (**UK**)	Deadline for commenting is 31 January 2017.
3.6	Simplification of exposure assessment (all PTs); initiated post WG-V-2016, relevant for PA authorisation/AS approval (**SECR**)	Deadline for commenting is 3 February 2017.

List of Attendees (Annex I)

Analytical methods and physico-chemical properties WG

Core members
MŰHLE Ulrike (DE) - Rapporteur
GATOS Panagiotis (EL)
WEBER Philippe (FR) – alternate member
HUIZING Tjaart-Jan (NL)
HUSZAL Sylwester (PL)
WARBURTON Anthony (UK)
CEBASEK Petra (SI) Rapporteur
Flexible members
KORKOLAINEN Tapio (FI)
KARHI Kimmo (FI)
CATALDI Lucilla (IT) - Rapporteur
THANNER Gerhard (AT)
HAVSLAND Stine (DK) - Rapporteur
CORDUA Birgitte (DK)
ILMARINEN Kaja (EE)
ÖSTERWALL Christoffer (SE) Rapporteur
Stakeholders
COGNAT Flore (CEFIC)
RANGGASAMI Nirmala (CEFIC expert)

Applicants
Saltigo GmbH
US ISC consortia / Lonza
Task Force Propan-1-ol / BODE
Fraunhofer
Sumitomo
Exponent
ECHA Staff
KREBS Bernhard (Chair)
AIRAKSINEN Sanna
GLANS Lotta
LISBOA MARTO Susana
MATTHES Jochen
SCHAKIR Yasmin

Human Health WG

Core members
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DE SAINT-JORES Jeremy (FR)
HOLTHENRICH Dagmar (DE)
KNEUER Carsten (DE)
BARRON Thomasina (IE)
BOS Carina (NL)
BRESCIA Susy (UK)
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ARAPAKI Niki (EL) alternate member
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WOBST Birgit (DE)
BRESCIA Susy (UK)
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CEDERBERG Håkan (SE)
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STRAUCH Stefanie (CH)

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ESTEVAN MARTINEZ Carmen
JANOSSY Judit
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DAMSTEN Micaela
CIOATA Nadia
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Bayer
BASF
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RANGGASAMI Nirmala – CEFIC (only for non-confidential items)

Efficacy WG

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GIATROPOULOS Athanasios (EL) – rapporteur
ATTIG Isabelle (FR)
MAXIMILIEN Yann (FR)
HAMEL Darka (HR)
GERRITSEN Lonne (NL)
MARCU Horatiu Antoniu (RO)
DUH Darja (SI)
JOHNSON Amy–alternate (UK) - rapporteur
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STRAUCH Stefanie (CH)
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