WG-IV-2017

Final minutes

03 January 2018

Minutes of WG-IV-2017

5 September - 14 September 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-IV-2017 (5-6 September 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 (AoB).

The following items were added to the agenda:

- Update of the Technical Agreements on Biocides (TAB)
- Update of the guidance for the assessment of technical equivalence

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 working group members.

5. Agreement of the draft minutes from WG III 2017

Comments on the draft minutes were received as follows:

Polymeric betaine: Greece

Any other business: The Netherlands

The draft minutes have been updated accordingly and distributed with the meeting documents. The working group members agreed on the modifications. No comments on the other parts of the minutes have been received.

The minutes of the working group meeting III in 2017 have been agreed by the working group members.

6. Follow up of previous working group meetings

6.1 Carbendazim

As a follow-up of the discussion of the APCP working group meeting II in 2015, a new 5-batch analysis was received by the eCA and an e-consultation was held in July 2017.

As a result of the e-consultation and the discussion at the working group meeting IV in 2017, the working group members agreed with the proposal of the reference specification and reference source.

6.2 Cyphenothrin

The substance was discussed at working group meeting II in 2017. Several points remained open that were followed-up by an e-consultation. The working group members agreed that the identity and naming of the active substance should be based on all eight isomers, in line with the ISO name.

The working group members agreed with the proposal of the reference specification and reference source.

7. Technical and scientific issues

7.1 Definitions used and applied

The chair updated the working group that following the e consultation on the document six working group members commented. An updated version of the document will be discussed at a future working group meeting.

7.2 Naming of active substances

The working group members discussed and agreed with the naming approach of active substances. For details please refer to the appendix 1.

7.3 Tolerance limits of active substances in biocidal products

The working group members agreed that there is no need to indicate explicitly tolerance limits in the Product Assessment Report (PAR) if applicants follow the Guidance on the Biocidal Products Regulation. In cases where the tolerance limits provided by the applicant are not in accordance with the guidance, then the differences should be stated in the PAR. For more details please refer to the appendix 2.

7.4 Distilled peracetic acid

The working group members discussed and agreed that distillation is a purification step in the manufacture. Hence, the purified (distilled) peracetic acid (PAA) should not be regarded as the same substance as the equilibrium PAA.

7.5 Early working group discussion on sulphur dioxide released from sodium meta bisulphite

All open issues were discussed and agreed by the working group members.

7.6 Early working group discussion on QUAT grafted to polymer backbone(s)

All open issues were discussed by the working group members.

8. Discussion on active substances

8.1 Empenthrin

All open issues were discussed and agreed by the working group members. The reference specification and reference source have not been set.

8.2 Penflufen

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

8.3 2-Phenoxyethanol

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

8.4 Active chlorine generated from sodium chloride by electrolysis

All open issues were discussed by the working group members. The reference specification and reference source have not been set but will be followed up by e-consultation.

9. Union authorisation

9.1 Iodine concentration increase in biocidal products containing iodine, iodide and iodate

The working group members confirmed that the system of iodide and iodated is regarded as a iodine generation system. However, the issue whether or not an iodine increase in biocidal products caused by this system may be acceptable was forwarded to the members of the coordination group.

10. Any other Business (AoB)

10.1 Update of the Technical Agreements on Biocides (TAB)

The working group members were informed that a version update of the TAB is available on CIRCABC for commenting within six weeks.

10.2 Update on the guidance for the assessment of technical equivalence

The working group members were informed that ECHA is working on an update of the guidance for the assessment of technical equivalence. The official procedure, including the partner expert group (PEG), will be initiated at the end of 2017 or beginning of 2018.

Minutes of Human Health WG

WG-IV-2017 (5 September - 7 September 2017)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 26 participants present, of which nine were core members and one alternate core member. 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.

Invitations to applicants are still sent via email as contact details in R4BP 3 are often not updated. It is also considered difficult to find relevant messages in 'Events history'.

For early WG discussions, the eCAs have to provide discussion tables and other meeting documents to the applicants as there is no specific case in R4BP 3.

Only official email addresses are accepted in S-CIRCABC and other communication. Common (team) accounts are not allowed.

The invitations to WG meetings are sent approximately 5 weeks before the meeting, and there will be no more the possibility to accept last minute registrations.

The members were requested to indicate in webropol if intending to be present only for a specific substance, or if not being present full days.

The WG-V-2017 provisional schedule has been uploaded on S-CIRCABC.

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-III-2017

The minutes were agreed without changes.

6. Discussion of active substances

6.1 Early WG discussion: Peroxyoctanoic acid generated from octanoic acid and hydrogen peroxide (eCA FR) PT 2, 3, 4

The discussion focused on seeking agreement on the questions asked during the e-consultation and concerned the waiving options with regard to the data package on POOA,

the option whether to derive or not systemic reference values and perform local risk assessment. It also clarified whether the risk to other substances of the equilibrium (i.e. octanoic acid, hydrogen peroxide, acetic acid and peracetic acid) needs to be addressed at active substance or product authorisation stage.

6.2 Penflufen (eCA UK) PT 8

The WG agreed on all the open points. The main discussion was on the impurities in the toxicological batches, the derivation of the references values and assumptions to be used in human exposure estimation.

6.3 Empenthrin (eCA BE) PT 18

The discussion points concerned reference value derivation, absorption values, human exposure assessment and how to deal with the lack of sufficient information on the carcinogenicity endpoint. Some of the points will be closed in an ad hoc follow-up.

6.4 Active chlorine generated from sodium chloride by electrolysis (eCA SK) PT 1-5

The discussion concerned reference value derivation, disinfection by-products, dietary risk assessment and human exposure assessment. All points were closed.

6.5 Phenoxyethanol (eCA UK) PT 1, 2, 4

The discussion concerned the batches tested and proposed specification, the reference values derivation, human exposure assessment and dietary risk assessment. Ad hoc follow-ups will close the points regarding the reference values derivation, exposure assessment and dietary risk assessment.

6.6 Early WG discussion: KMPS - Pentapotassium bis(peroxymonosulphate) bis(sulphate) (eCA SI) PT 2-5

The discussion concerned the assessment of the completeness of the toxicology package, the acceptability of the proposed waivers, the risk assessment approach (local vs. systemic) and preliminary discussion on the reference values derivation.

6.7 Early WG discussion: Prallethrin (eCA EL) PT 18

The discussion focused on whether one CAR can be prepared summarising all data from both applicants on the substance, whether the batches used in the toxicological studies of both applicants support the specifications, and the completeness of the genotoxicity data package.

7. Discussion of Union authorisations

7.1 Update on Union authorisation

SECR gave an update on Union authorisation, by focusing especially on the experience with the first Union authorisation applications. SECR asked the WG members to provide their feedback by 29 September 2017 on the Union authorisation steps followed so far. A newsgroup has been created in S-CIRCABC for that purpose.

7.2 UA applications for product families containing Iodine/PVP-Iodine

For confidentiality reasons, the discussions points are not disclosed. For the details, please refer to the confidential minutes.

8. Technical and guidance related issues

8.1 Update on guidance development

SECR presented the current status of several guidance-related documents which are at different stages of development, including general documents as well as those developed in the context of the ad hoc Working Groups on Human Exposure (HEAdhoc) and Assessment of Residue Transfer to Food (ARTFood). The identified needs for further guidance development were also included. The document presented is available in S-CIRCABC to members and associated stakeholder organisations.

8.2 Recommendations of HEAdhoc

a) Proposal for harmonising the assessment of human exposure to repellents (PT 19) – (revision of HEAdhoc recommendation 11)

The WG members considered that the only relevant scenario to assess exposure to repellents is the mid-term scenario, while acute scenarios should not be assessed. A value of 55% for uncovered body surface area was agreed for the assessment of repellents with normal outdoor clothing.
The WG members considered that including a worst-case scenario exposure assessment with minimal clothing (e.g. a swimming suit) would create difficulties in the authorisation of those products in which a safe use can only be identified with normal outdoor clothing. MSCAs requested SECR to inform the Coordination Group about not performing a worst-case exposure assessment, asking whether the Coordination Group considers labelling requirements for clothing as an appropriate risk mitigation measure in order to identify a safe use.
The WG requested to include the date into force of the Revised Recommendation for the authorisation of biocidal products and agreed with the Recommendation after the inclusion of the changes mentioned above.

b) Exposure to anticoagulant rodenticides via sachets

The WG members considered that one value for the protection factor of paper sachets could be used for all kind of formulation types. The WG noted a higher protection factor could be expected for plastic sachets but in the absence of data a value for protection factor could not be set. Further investigations will take place within HEAdhoc with the aim of establishing a realistic protection factor for both paper and plastic sachets.

8.3 Rounding of reference values

The ECHA Guidance Vol III Parts B+C, or other ECHA Guidance, does not inform how reference values should be rounded. In previous WG meetings, members have proposed to apply the principles established by EFSA. Following a SECR proposal, the following was agreed to be included in the Technical Agreements for Biocides:

> **How should reference values be rounded?**
>
> For the rounding of reference values (AEL, AEC, ADI, ARfD), the principles should be applied that are presented on pages 24-25 of the EFSA Opinion *Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured Data*; EFSA Journal

2012;10(3):2579 (https://www.efsa.europa.eu/en/efsajournal/pub/2579): "*Derived values, such as health-based guidance values, should be rounded to a single significant figure if the impact of rounding is less than 10%, and to two significant figures if the impact of rounding to one significant figure exceeds that percentage. Rounding should happen as late as possible in the assessment process.*"

This agreement concerns reference values that are normally derived from NOAEL/NOAEC values by applying assessment factors. It does not concern measured values such as absorption values or NOAEC/LOAEC values used in e.g. local risk characterisation.

8.4 Definition of relevant impurities

This second discussion on clarifying the definition of relevant impurities took place following an e-consultation. SECR provided in a meeting document all the input submitted to the e-consultation.

The current guidance is considered to allow two different interpretations of the definition of a relevant impurity. The definition is not clear on whether the concentration of the impurity plays a role in deciding on the relevance of an impurity. The question is whether it is only 1) the hazard properties of the impurity (in comparison with the hazard profile of the active substance) that determines the relevance, or whether 2) the concentration of the impurity should also be taken into consideration. The discussion focused on the pros and cons of these two options.

SECR noted that preferably, an alignment of the approaches for pesticides and biocides should be maintained, and SECR will therefore work together with EFSA in trying to clarify the definition.

Several members considered that option 2 would also capture changes in concentration of very hazardous impurities, unlike some members suggested in the e-consultation. The manufacturers need to meet the specification, and increases of impurities would not be acceptable. It would therefore not make sense to identify an impurity as relevant if it is not of concern at the concentrations allowed in the specification.

Some members considered option 1 to better support a harmonised approach. Furthermore, the methodology for option 2 is not yet available but could be developed.

The members recognised that if impurities are considered as not relevant based on their low concentration, then in the current guidance increases in the impurity concentrations might be acceptable in Tier I that could have an impact in e.g. C&L. SECR noted that if concentration is agreed to be taken into account, then the guidance on Tier I assessment would also have to change. One member added that C&L is a responsibility regardless of whether an impurity is relevant.

It was pointed out that the concept of relevant impurity would not make a difference with regard to C&L, because in any case the specific or generic concentration limits would drive the need to classify.

The example of 10 % additional toxicity was considered arbitrary, recognising however that it was an example taken from the WHO guidance. Furthermore, the differences in calculation rules with respect to the C&L calculation rules could be problematic.

One member considered that hazard properties as such are taken into account in the C&L of the substances, but taking into account the concentration would in general be the best way to regulate chemicals – except for non-threshold genotoxic and/or carcinogenic compounds and possibly PBT substances. Special consideration would also need to be applied to extremely toxic chemicals like aflatoxins and dioxins.

The CEFIC representative supported option 2, among other things because less information on the impurities would become publicly available. Such information can be used by competitors in e.g. deducing the manufacturing process.

SECR pointed out that the applicant needs to analyse all impurities above 0.1 % and all relevant impurities below that concentration. Therefore, in deciding on how to perform the analysis, also the applicant has to consider the definition of relevant impurities.

Overall, option 1 was considered as possibly more precautionary. However, many members considered that this may not be the case and that option 2 would capture the same possible risks. SECR clarified that in either case the level of protection should not be reduced and if any problems are identified due to changing the definition, these would need to be covered by other changes in the guidance.

The members considered that the two options may not be as far from each other as it could initially seem, and it might also be possible to combine some aspects of both. Regardless of the definition, it would also be necessary to clarify in the guidance what information should be considered sufficient to consider that the impurity may have the toxic properties making it relevant (e.g. whether QSAR information would be sufficient).

9. Any other business

9.1 Other information & lessons learned

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. It would be most helpful if the document could be provided together with the CAR or with the RCOM, but it should be submitted at the latest together with the updated RCOM (step 15 of working procedure). This document should be provided by filling in Chapters 14.1 *Critical endpoints* and 14.2 *Reference values* of the draft CAR template.

The document was supported and considered very useful for the eCA and for the WG meeting. The information is already included in the CARs that are prepared according to the new format.

E-consultation on genotoxicity assessments

An e-consultation was launched on 24 May for a document provided by SE "*Evaluation of the mutagenic potential in vivo for substances concluded to be mutagenic in vitro - Key issues to take into consideration*". The deadline for comments was 27 June 2017. Due to similar issues discussed in an EFSA Opinion with public consultation until 9 September, SE decided to wait until the EFSA Opinion is finalised before deciding whether to proceed with a separate document.

Guidance repository

Noting that new guidance does not always apply immediately to applications, it is often necessary to refer to previous versions of the guidance. A new web page will be created for replaced/updated guidance and a link to this page will be included in the BPR Guidance page (https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation). The page is expected to be available in October 2017.

Transitional guidance

Transitional guidance that was developed under BPD has been kept at the ECHA website until new (ECHA) documents are available. The site will be closed when Vol IV is published in September 2017.

Endocrine disruptors – guidance and implementation

SECR informed the members of the most recent developments and the expectations regarding the guidance and implementation. All these will depend on the adoption of the criteria.

Problems in reference specifications

The reference specification is a key element of the assessment and should be the starting point for the evaluation. There are several recent examples of substances with complications due to problems in the reference specification. These problems have been mostly related to the identification of relevant impurities and to the question whether the reference specification is supported by the toxicity testing. SECR asked the evaluating CAs to take this experience into account in ensuring, as far as possible, that the assessment is performed according to the current standards before submitting the CAR for peer review.

Additional information provided after the trilateral discussions

SECR informed that during discussion table preparation, it is very difficult to manage additional information received and ensure that appropriate information is provided to the members and applicants. SECR requested the members to make every effort to ensure that all information is available at the time of submitting the updated RCOM.

Early WG discussions

SECR asked the members to proactively consider requesting for an early WG discussion at least if it is unclear whether the risk characterisation should be systemic and/or local, and if there is extensive waiving in the dossier.

Next WG meetings

The timing of the next Human Health WG meetings is provisionally planned as follows:

- Human Health WG-V-2017: 21-23 November (Tuesday-Thursday)
- UA – virtual WG meeting: 4-5 December (Monday-Tuesday)

Ad hoc follow-ups

An ad hoc discussion took place regarding the number of ad hoc follow-ups and the inefficiency of the process.

Several members criticised that the agenda was too fully packed and too little time was reserved for active substance discussions. SECR agreed, noting however that the timing has to be decided before having a clear understanding of the issues to be discussed for each substance. In general, ad hoc follow-ups were seen as an inefficient way to reach agreements and instead, the preference should be to solve any issues during the WG meetings.

The following proposals were made to reduce the number of ad hoc follow-ups:

- The WG agenda should allow more time to the active substance discussions. The general items related to e.g. guidance should have more flexibility so that more time can be taken for active substances if needed. This is however already implemented and substance discussions do have the priority.
- The members and especially the eCA should make more effort to close points during the trilateral discussions. SECR noted that when a substance has an unusually high number of open points, it is unlikely that all of them could be closed in the given time.
- When submitting the updated RCOM, the eCA could indicate how much time is needed for the WG discussions (this was however not considered realistic).
- There should be a maximum amount of substances for a WG meeting.
- SECR could make more proposals to close points, similarly as there are currently "provisionally closed points".

The following proposals were made to better handle ad hoc follow-ups:

- Teleconferences for the ad hoc follow ups were supported as a more efficient tool than the written procedure.
- Flexibility regarding the people attending the teleconferences should be allowed.
- Dates could be agreed in advance for ad hoc follow-up teleconferences. SECR supported this in principle but noted that this would be difficult for many reasons, e.g. because launching an ad hoc follow-up depends on a proposal to be submitted by the eCA, and the timing of a proposal depends very much on the question to be solved.

SECR noted that for the next meeting, the Human Health WG will take place during the latter week of a two-week WG. According to the timelines, the discussion tables would thus be provided 17 days before the WG instead of the normal 10 days. SECR asked whether the members would prefer receiving the discussion tables according to the timelines (17 days before the meeting), or whether they would prefer SECR to intend closing further points and providing more proposals during the additional week, providing the discussion table 10 days before the meeting. The members supported providing the discussion table 10 days before the meeting and making an effort to close points and prepare proposals for closing points.

Minutes of Efficacy WG

WG-IV-2017 (6 September – 7 September 2017)

1. Welcome and apologies

The Chair welcomed all participants to the 18th Efficacy WG meeting. There were 7 core and 1 alternate member who participated in the meeting. In addition, 9 flexible members, 5 experts and 3 ASO representatives 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. SE proposed to add to the agenda under AOB a short discussion related to efficacy claims. The Chair informed that the possible discussion on it depends on the time availability as the agenda for this meeting seems to be fully packed. The EFF WG 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-III-2017

The Chair informed that comments for the minutes of WG-III-2017 had been received from FR and the applicant for PHMB. The draft minutes version was amended in relevant parts and agreed by the EFF WG.

6. Discussion of active substances[1]

6.1 Empenthrin (eCA BE)

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 Active chlorine generated from sodium chlorine by electrolysis (eCA SK)

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.

6.3 Penflufen (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.

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

6.4 Phenoxyethanol (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.

6.5 Early WG discussion: Ozone (eCA DE)

There were four discussion points in the discussion table for a new active substance *in situ* system "Ozone generated from oxygen", which is currently assessed for product types (PTs) 2, 4, 5 and 11. The discussion points were related to various modifications of one of EN test method to prove the efficacy of the *in situ* system.

Considering the submitted information, it was agreed by the EFF WG members that the EN test can be modified for vortexing, provided that this modification is validated and justified. The EFF WG also discussed whether it would be acceptable to decrease soiling and bacterial load. It was concluded that decrease of soiling is acceptable for some PTs. The decrease of bacterial load was not accepted by the EFF WG.

To have more realistic conditions of use, the EFF WG agreed that repeated ozone dosing is acceptable, if a test will be developed and properly validated. The concentration of ozone should be monitored during the test.

The EFF WG also agreed that the German simulated use test *'Quantitative determination of the efficacy of drinking water disinfectants'* is acceptable.

Regarding the proposed test modification with *Legionella*, it was pointed out by the EFF WG members that in the EN standard the soiling is already decreased. Nevertheless, the decrease of *Legionella* concentration is not acceptable. A matrix with different concentrations, however, could be done. A simulated use test or a field test should also be provided.

Regarding suitable efficacy test for biocidal product authorisation, the competent authority in which the authorisation is sought should be consulted before submission of an application for authorisation. All relevant guidance updates should be considered as well.

7. Discussion of Union Authorisations

7.1 Update on Union authorisation (ECHA)

Due to time limitation the update on UA was provided to the EFF WG in S-CIRCABC, and a newsgroup was opened to enable commenting.

7.2 UA applications for product families Iodine/PVP-Iodine

Two biocidal product families based on iodine/PVP iodine were discussed. There were two remaining open points for the first product family. The EFF WG agreed to add a general sentence to the directions of use in the SPC, and accepted the justification given by the eCA on the modification of the EN test conditions.

There were four remaining open points for the other product family. The EFF WG agreed on the justification given by the eCA on the modified EN test. The EFF WG discussed whether bacterial species tested in addition to those stated in the corresponding EN test should/can be listed in the SPC. It was concluded that in case the target organisms are bacteria, specific bacterial species names should not be listed in the SPC. The EFF WG also agreed to add a general sentence to the directions of use in the SPC, and to add an instruction sentence on the use temperature of the products into the SPC.

In relation to the discussion of UA applications the EFF WG members asked whether IUCLID 6 file and especially annotations need to be updated according to the agreements made. Since this is a general issue not related only to efficacy the ECHA SECR proposed to have exchanges with other WGs.

7.3 Early WG discussion on UA applications for biocidal product families containing Propan-2-ol

During the evaluation of UA applications for biocidal products/product families based on propan-2-ol the eCAs identified issues to be clarified in the context of the coordination role of ECHA SECR. In the subsequent discussions the issue of how virucidal claims might be worded on the label was left for EFF WG-IV-2017. The EFF WG noted that the WG agreements can only be made on the text in the SPC, not on the product label.

The WG agreed to include further information on virucidal claims (full virucidal claim, claim against enveloped viruses, limited spectrum virucidal claim) into ECHA Efficacy WG site. A link to this site can then be provided in the SPC.

It was agreed that AT will draft a text proposal and send it to ECHA by the end of September 2017, for discussion in WG-V-2017.

SECR NOTE: It was reported by the NL after the EFF WG meeting that CEN WG5 is drafting a document on 'Concepts and ideas for a position paper about the preparedness in case of an outbreak of emerging or re-emerging viruses – a topic that would be of interest to experts in all CEN member states'. NL offered to ask CEN, if this document can be shared and used as a base for the EFF WG proposal.

There was no clear conclusion on adding names of example virus species into the SPC. The EFF WG agreed that an ad hoc follow-up will be launched in order to collect proposals of example viruses, with help of national experts. After having the draft proposal, the EFF WG will conclude whether example virus species will be included in the SPC.

8. Technical and guidance related issues

8.1 Update on guidance development (ECHA)

Due to time limitation the update on guidance development was skipped. The EFF WG members were informed that relevant presentation is available for comments on S-CIRCABC.

8.2 Revision of Volume II/A (ECHA)

The revised versions of Volume II, Part A and relevant sub-sections of Volume I Part A – *Information requirements* were discussed by the EFF WG members.

The EFF WG members were informed that the decision how to proceed with respective sub-sections 7.5/7.6/7.7/7.10 of Volume I Part A will be communicated at later stage after discussion and agreement with other WG chairs and ECHA Guidance unit.

In relation to the user categories (Section 7.4.) the EFF WG proposed to include a footnote explaining that in other sections and Volume II, Parts B+C the term "professional users" encloses also "trained professional" and "industrial" users.

The EFF WG discussed the different terms used in Volume II Part A related to the efficacy assessment and conditions of use of the biocidal product. In different parts of Volume II Part A different phrases are used, i.e. normal, realistic or worst case conditions of use. An agreement was not reached by the EFF WG. This point will be flagged for PEG consultations.

It was also agreed by the EFF WG members to include into Volume II Part A, III Section 6.7. a link to ECHA Efficacy WG site, where the check list for efficacy tests for preservatives will be provided.

The revised versions of Volume I Part A and Volume II Part A presented during the meeting were agreed by the EFF WG members with some minor amendments, and will be sent for PEG consultations by ECHA.

8.3 Preservatives – check list for efficacy tests

This point was discussed together with agenda item 8.2. The check list, a tool for the applicants to plan testing and for the eCAs to evaluate the tests, was presented by SE. The EFF WG members proposed to:

- column 1 - split into two separate columns;
- column 2 - remove the phrase: "*i.e. the material becomes deteriorated by microbial growth under the given use conditions"*;
- column 5 - remove from the phrase: "*i.e. in which way do they deteriorate the matrix?"*;
- column 6 - rewrite the text into: "*Is the test protocol depicting a relevant end point?"*;
- column 8 - rewrite the text into: "*Have the controls (i.e. growth) been validated according to a relevant guidance or standard document?"*;
- column 9 - rewrite the text into: "*Has the intended inhibition/killing/controlling effect of the harmful organisms occurred and does it fulfil the requirements set by a relevant guidance or standard document?"*;
- add a phrase "*Expert judgment"* in empty cells in row "Test not acceptable if".

Footnotes with respective explanations will be added. SE will send the updated version to ECHA as soon as possible. This table will be published on ECHA Efficacy WG site.

8.4 PT 8 post – PEG question

After PEG consultation of Appendix 4 of the PT8 efficacy guidance related to Annex A of EN 599-1 the remaining open points were discussed by the EFF WG.

After the discussion the most important changes are listed below:

- The use of term "carrier" instead of/additionally to the term "solvent" in the guidance. It was agreed that a footnote will be given with the clarification of the terms "solvent" and "carrier". EWPM will draft this footnote and send it to ECHA;
- Sub-section A.2.2 g will be added. FR will send the text of this section to ECHA;
- The sub-section A.2.3 d was rewritten during the meeting into: "*In a case of inorganic active substances (e.g. copper II salts), no additional biological testing is required when changing the inactive component (the anion part) of the active substance not resulting in a change in the ratio, total content or chemical properties of biocidal active component (e.g. copper II)";*
- In the sub-section A.2.3 f it was added: "*Changing or adding a water miscible co-solvent (distillation ranged as in A.2.2 b) up to 5% of the total formulation";*
- In addition the EFF WG agreed to add the following in Volume II, Parts B+C, section 5.5.8.2.2.3:
  - "*Products which only claim protection against blue stain can be authorized for uses where exemption of the requirement for efficacy against wood destroying fungi can be justified, e.g. for wood or wood products that by their nature are not susceptible to brown rot fungi. Pure anti-blue stain products may not be used together with product against wood destroying fungi to prevent double treatment of two fungicides*" (see agenda point 8.5).
    - *"The test species used will depend upon the label claims and will include as a minimum the beetles spp. for Use Class 1. Use Class 1 products are only insecticides.*

      Products used as wood preservatives with only insecticide activity can be authorised for preventive use only in UC1. For UC2 and higher classes,

efficacy against basidiomycetes must be demonstrated as a minimal requirement. This clarification (of interpretation of test species) should be considered to be effective immediately (and applying to on-going assessments) and not subject to the standard transitional period of 2 years for new guidance".

The paragraph (sub-section A.2.2 d+e) "*Due to the **potential** impact of pigments on penetration it was decided to allow changes only up to the former content of pigment (solid portion) in the formulation when the 'no additional testing rule' must apply. If the exact content of the pigment and its solid portion is unknown changes up to the former content of the pigment paste are allowed if robust justification is provided.*" will be flagged for CAs consultation, in order to consider Article 17(6) of the BPR.

DE informed that shortly before the EFF WG meeting a proposal concerning this paragraph was sent to ECHA. It is uploaded on non-confidential part of S-CIRCABC in the WG-IV-2017 folder: *WGIV2017_EFF_8-4_PT8_Post PEG questions_DE comments*. DE will raise this issue during CAs consultations.

The updated Appendix 12 (new numbering in accordance with Volume II, Parts B+C) will be sent for CAs consultations.

8.5 PT8 – Mandatory requirement for testing according to EN 599-1 for Use Class 3 (DK)

DK proposal concerned the possible waiving of the mandatory requirement for testing according to EN 599-1 for Use Class 3, in case only protection against blue stain is claimed. The example was provided by Danish Window Manufacturer, which develops windows and external doors using 2ØKO system. 2ØKO system is based on using pine heartwood, and assembling window frames in a specific way (system). This system is used in combination with paint system with only limited amount of biocides. Upon certification of the whole system (used wood material, assembly of the product), protection against only blue stain fungi is needed.

However, in accordance with the existing Volume IIA, Part B+C and EN 599-1 in all cases testing against wood rotting fungi (Use class 2, 3, 4 and 5) is necessary.

After the discussion the EFF WG agreed to include in Vol II, Parts B+C a sentence clarifying that in some cases, when claim against only blue stain fungi is made, justified exemptions are possible. The respective sentence will be included in the Volume II, Part B+C, Section 5.5.8.2.2.3 (before Use Class 1). See agenda point 8.4 above.

8.6 PT18 – Clarification on tests needed for a general claim against 'Other arthropods' (ECHA)

Due to the time limitation this agenda point is postponed for discussion in EFF WGV2017.

9. AOB

9.1 Mutual recognition disagreement (closed session)

The discussion concerned two PT19 biocidal products with the efficacious application rate different from the dose used in the exposure assessment.

The EFF WG focused on four questions:

1. Does the EFF WG consider the application rate used in the field study for mosquitoes as unrealistic?

   Regarding the mosquitoes' biting pressure in the field trial, the EFF WG pointed out that there is no valid justification to consider this biting pressure as high. In addition, it was also indicated that high biting pressure relates rather to the arm-in-cage test than to a field test. Therefore, the EFF WG did not consider the application rate used in the field studies for mosquitoes as unrealistic.

2. Does the EFF WG consider that in the 'arm-in-cage' test against ticks an unrealistic application rate was used?

The EFF WG members pointed out that the conditions in the 'arm-in-cage' test against ticks cannot be considered as a worst case scenario as is the case with mosquitoes. The test conditions and application rate in the test submitted by the applicant were in accordance with the applicable methodology. Therefore, the EFF WG did not consider that in the arm-in cage test against ticks an unrealistic application rate was used.

3. Does the EFF WG accept the discrepancy between the application rate derived from the efficacy studies and the dose rate used in the risk assessment for PT19 biocidal products taking into account that a similar approach as for the DEET containing products could be followed, i.e. revision of the assessment at the product renewal stage and immediate applicability of any new agreed guidance addressing the above-mentioned discrepancy? If so, does this mean that the conditions in Article 19(1)(b)(i) are met at the application rate used in the exposure assessment?

   The EFF WG did not accept the discrepancy between the application rate derived from the efficacy studies and the dose rate used in the risk assessment. This applies to the cases discussed at WGIV2017, and to any other possible future cases.

4. Are there any efficacy tests (other than the 'arm-in-cage test') or standard protocols for both laboratory and field tests at a lower, realistic dose rate currently available or under development?

   For the time being there are no available efficacy tests/standard protocols testing a realistic efficacious dose. Only some modifications of existing tests/protocols with lower doses are possible. Nevertheless FR added that they currently evaluate dossiers where lower doses (equivalent to those used in risk assessment) are used in arm-in cage tests with correct time protections, pretty similar to those obtained with full doses.

9.2 Room disinfection – how to ensure proper use (NL)

The EFF WG agreed that for biocidal products used as room disinfectants the advice for biological validation and, in cases where there are monitoring methods available, also the advice for chemical validation should be included in the use instruction on the SPC.

Cefic will comment this draft conclusion by 10 October 2017 (due to problems with S-CIRCABC the working document was circulated to Cefic members only shortly before the EFF WG meeting).

9.3 Textile disinfection (NL)

The EFF WG agreed on the following:

1. Efficacy testing.

   For biocidal products used as disinfectants in combination with detergents the following approach should apply:

   - Phase 2 step 2 test should be done according to EN 16616. Furthermore as a minimum the disinfectant/detergent combination should be tested. In principle all claimed disinfectant/detergent combinations and various conditions should be tested, unless worst case conditions can be justified.
   - Phase 2 step 1 test should be done in combination with the detergent and disinfectant. All claimed disinfectant/detergent combinations and various conditions should be tested.

   For biocidal products used as disinfectants and applied separately from the detergent:

   - In case a disinfectant is applied in a such way that it does not come into contact with a detergent, a justified suitable test procedure for the Phase 2 step 2 test should be provided, e.g. a modified EN 16616 test without detergent, with justification for the use of soiling that mimics the clean conditions. To demonstrate efficacy in this modified test, test organisms should be added at the same step of the process as the disinfectant.

- Phase 2 step 1 test should be performed without a detergent.

For combined cleaner-disinfection products:

- EN 16616 can be done with the product without adding an extra detergent.
- Phase 2 step 1 test should be done with the product.

2. In table 1 *Efficacy testing versus disinfection at various steps of the washing process,* in the column test conditions it should be added that disinfectant should also be used at use concentration: detergent and disinfectant at use conc.
3. The proposal *'Overview of test organisms versus temperature'* presented in Table 2 in the working document was in general agreed by the EFF WG. For temperatures 40C°<Temp<60ºC *Enterococcus hirae* is replaced by *Enterococcus faecium* (in the EN test *Enterococcus faecium* is the test organism for temperatures above 60°C) as a test organism. Fungi and mycobacteria should be tested only if a specific claim is made.
4. Whether detergents can be mentioned in SPC under other information could not be agreed by the EFF WG, and should be clarified by the CG. NL will raise this issue at CG level.
5. Regarding standard detergent it was agreed that Cefic will enquire their members for suggestions.

9.4 Other information & lessons learned (ECHA)

The presentation was skipped due to the time limitation. The EFF WG members were informed that the presentation will be uploaded on non-confidential part of S-CIRCABC and comments/questions can be sent to the WG FMB.

Minutes of Environment WG

WG-IV-2017 (12 September - 14 September 2017)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 24 participants present, of which ten were core members (two represented by alternates) and eleven flexible members in addition to one advisor and two rapporteurs. Representatives from accredited stakeholder organisation were present for agenda item 8 and 9. 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.

Invitations to applicants are still sent via email as contact details in R4BP 3 are often not updated. It is also considered difficult to find relevant messages in 'Events history'.

For early WG discussions, the eCAs have to provide discussion tables and other meeting documents to the applicants as there is no specific case in R4BP 3.

Only official email addresses are accepted in S-CIRCABC and other communication. Common (team) accounts are not allowed.

The invitations to WG meetings are sent approximately 5 weeks before the meeting, and there will be no more the possibility to accept last minute registrations.

The members were requested to indicate in webropol if intending to be present only for a specific substance, or if not being present full days.

The WG-V-2017 provisional schedule has been uploaded on S-CIRCABC.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the WG members to provide any additional items. 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 was declared.

The Chair declared an interest with one of the applicants, which however was not judged as a conflict of interest.

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

The minutes were agreed without further changes.

6. Discussion of active substances

6.0 Update on the status of Prallethrin

The outcome of the e-consultation (conducted in July-Aug 2017) was reported by the SECR. The proposal of the eCA was agreed by the commenting members in the e-consultation. Therefore, there was no need to have an early WG discussion by the ENV WG.

6.1 Empenthrin (eCA BE) – PT 18

Five points related to effect/hazard assessment, one point on PBT assessment, one on the updated risk assessment and one point related to the exposure assessment were discussed. In addition, one point on risk mitigation measures was discussed but not concluded since outside the WG remit. All points but two were closed, the two open items will be followed up by an ad hoc follow up.

Actions:
- Two ad hoc follow ups to be initiated by SECR (eCA to prepare the respective documents).
- **TAB** entry: The WG agreed to include the default value of 2.5 for the number of wardrobes per household in the TAB together with an explanation how the value was derived. When preparing the TAB entry, the size of the wardrobe needs to be further clarified (cross-check with CONSEXPO).

6.2 Active chlorine generated from sodium chloride by electrolysis (eCA SK) – PT 1-5

Five points related to exposure and risk assessment were discussed. All points were closed during the meeting and 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:
- Item to be forwarded to **BPC/CA** meeting: inclusion of the risk assessment of disinfection by-products at the AS renewal stage or at product authorisation stage?

6.3 Penflufen (eCA UK) - PT 8

Two points related to effect assessment and one point related to exposure assessment were discussed. One additional point related to effect assessment was presented for information only as it had been closed after the distribution of the discussion table for the meeting. All the discussed points were agreed and closed.

Action:
- **TAB** entry: for the service life for the longer storage period on a storage place a default value of 7300 days (20 years) should be used, in line with the decision previously taken for PT 7 (i.e. in line with TAB v1.3, entry ENV 81).

6.4 Phenoxyethanol (eCA UK) - PT 1, 2, 4

One point related to effect assessment was discussed. The point was closed during the meeting meeting and 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.

6.5 Early WG discussion: Exposure assessment sulphur dioxide (eCA DE) - PT 4, 9

The need for an early WG discussion was identified in relation to the exposure assessment two dossiers 1) SO_2 generated from sulphur by combustion (PT 4) and 2) SO2 generated in situ from sodium metabisulphite by reaction with water (PT 9).

The WG agreed with the proposed exposure assessments adopted for PT4 and PT9 uses. The WG agreed also with the used background and reference concentrations for both PTs.

Actions:

- **TAB** entry: scenarios provided for PT 4 and PT 9 for the described uses.

6.6 Transfluthrin – New endpoints after AS approval (eCA NL)

Four points related to new endpoints made available after the approval of the active substance were discussed and agreed. The outcome of the discussion can be forwarded to the BPC meeting.

Actions:

- SECR to initiate e-consultation to clarify the DT50 value (not discussed at the WG meeting).

7. Discussion of Union authorisations

7.1 Update on Union authorisation

SECR gave an update on Union authorisation, by focusing especially on the experience with the first Union authorisation applications. SECR asked the WG members to provide their feedback by 29 September 2017 on the Union authorisation steps followed so far. A newsgroup has been created in S-CIRCABC for that purpose.

7.2 a/b UA applications for product families containing Iodine/PVP-Iodine (eCA NL)

Two applications were discussed. All points were closed, the Working Group members agreed on the evaluation of the eCA. The eCA can prepare the updated PARs and proceed to the Biocidal Products Committee.

Actions:

- **TAB** entry: clarification that sorption onto suspended matter can be considered in the PECsw calculation.
- SECR to follow up the general question if the approach for sewage sludge application as provided in EUSES/Vol IV Part B can be transferred also to application of manure with regard to consideration of k_{leach} in the total removal constant.

8. Technical and guidance related issues

8.1 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).

8.2 Conclusions 2nd PT 18 EG meeting (ECHA/EG)

This agenda point covered three main groups of items:

1. **Pending actions from the 1st PT 18 EG meeting:**

The conclusions of the 2nd PT18 Expert Group (EG) meeting on two remaining open items originally discussed at the 1st PT18 EG meeting were presented for confirmation to the ENV WG. The WG re-confirmed the conclusion of the EG. One item remained open, to be followed up.

Actions:

- SECR to launch an e-consultation of the PT18 EG on the open item.

- SECR to include all agreed items in the **TAB**.

2. PT 18 high/medium priority issues from the 2nd PT 18 EG meeting

The SECR presented the conclusions of the 2nd PT 18 EG meeting (PT 18 household and professional uses) on the highest and high priority items, for confirmation to the ENV WG. Two points remained open after discussion. Due to time constraints, the conclusions on the medium priority issues were not discussed and it was agreed to follow up on these via a written procedure.

Actions:

- SECR to launch an e-consultation on the remaining open high priority items and on the not yet discussed conclusions of the EG on medium priority items.
- SECR to include all agreed items in the **TAB**.
- Specific actions:
  - DT item 7: **SECR** to check applicability of the document prepared by DE on input parameters for FOCUS modelling. Deadline: **15 October 2017**.
  - DT item 16: Ad 1 – **FR** to share feedback on the survey currently ongoing in France (DE may support FR). Deadline: **WG-I-2018**.
  - DT item 16: Ad 3 – **SECR** to check TM minutes and follow up with **UK** (to report back at WG-I-2018). Deadline: **WG-I-2018**.
  - DT item 11: Ad 6 – **NL** to share the study on this matter with the other EG experts. Deadline: **15 October 2017** (*Post-WG meeting note: SECR already received the studies*)

3. PT 18 low priority issues from the 2nd PT 18 EG meeting

Due to time limitations, the outcome of the e-consultation of the PT 18 EG on the low priority items (not discussed at the 2nd PT 18 EG meeting) was not discussed. The ENV WG agreed to follow up on these items also via written procedure.

Action:

- **SECR** to launch an e-consultation on the proposed EG conclusions on low priority items.

8.3 Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19

The SECR presented 22 items for discussion related to emission estimations in different product types (PT 8, PT 10, PT 13 and PT 19). The items were raised by MS, e.g. through a dedicated Newsgroup or during the validation exercise of the 1st draft for the spreadsheets for PT 8 and PT13, and also some were raised by the SECR. The majority of the items was closed. For two of the items the WG agreed to proceed with an e-consultation and for several other items follow up actions were agreed and are provided in the following.

The detailed conclusions are provided in Appendix 2 below.

Actions:

- **SECR** to launch an e-consultation of the ENV WG on item 13 and item 14 of the discussion table.
- **SECR** to include all agreed items in the **TAB**.
- Specific actions:
  - DT item 2: Ad 1 – **SECR** to check if extension to roof with the proposed parameterisation in the ESD for PT 8 is feasible, prepare a proposal and share with WG. Deadline: **15 October 2017**.

- DT item 3: **NL** and **DE** to provide to the SECR their respective description of how they generate leaching rates/cumulative emissions, as presented at the meeting. **SECR** to include in the minutes. Deadline: **28 September 2017**.
- DT item 5: **NL, DE, UK** and **DK** to provide to the SECR how they interpret semi-field leaching studies, how they calculate the cumulative leaching at Time 2 and how extrapolate beyond 1-2 years. **SECR** to include in the minutes. Deadline: **28 September 2017**.
- DT item 8: **NL** to provide comments on the topic; **DK** to share their scenario on treatment of windows and door frames. **SECR** to include in the minutes. Deadline: **28 September 2017**.
- DT item 10: **NL** to provide their Excel sheet with an explanatory note to FR and DK. **FR** and **DK** to cross-check (to be presented to **ENV WG** for agreement). Deadline: **15 October 2017.**
- DT item 12: **NL, DK** and **FR** to check the implication of the change of taking into account the default values for suspended matter instead of the default values for sediment (as reflected in eq 50 in Vol. IV part B). **CEFIC** to provide their comments to SECR. Deadline: **15 October 2017**.

8.4 Open items TAB v1.3 (for clarification in preparation of TAB v1.4) (ECHA)

Comments of WG members on entries for TAB v1.3 ENV, which were not implemented in the TAB version, were discussed:

1. *TAB entry ENV 9: Use of the model SimpleTreat 4.0 for biocides*

The item related to the change of SLR and BOD was no longer relevant due to the new SimpleTreat version, where parameters can be changed. Therefore the text in TAB does not need any adaptation.

2. *TAB entry ENV 19: Freundlich adsorption coefficient to be used in FOCUS models*

The following revised text was proposed, which was agreed: "The Applicant performs a full OECD 106 batch sorption study at five concentrations covering preferably two orders of magnitude and derives reliable 1/n values. Here, the arithmetic mean of the empiric 1/n values should be used in the FOCUS model".

3. *TAB entry ENV 42: Medical sector: disinfection of endoscopes*

The equation to calculate the maximum emission rate to water $Elocal_{water}$ (once-through) should be:

$$E_{local3,water} = N_{rep-max} * Q_{machine} * 10^{-6} * C_{disinf} * e^{-kdegdisinf * Trepl}$$

The WG further agreed that the text in the TAB should be corrected since *Fcarry-over* is not relevant for once-through treatment.

4. *TAB entry ENV 135: Refinement of risk assessment: reduction of treated skin surface area and taking into account dermal adsorption*

The WG agreed to keep the current text including the proposed correction ("*As first tier for the treated skin area, the value as proposed in the recommendation of the Ad hoc WG on Human exposure should be used, i.e. 64%* of 16600cm², i.e. 10660 *cm²")*, clarifying the calculation of the agreed default value. SECR to include a reference to the HEAdoc Webpage in the TAB entry.

5. *TAB entry ENV 137: Consolidated list of technical agreements – Environment*

Concerns were raised on the leaching correction factor of 2.9 provided in the "consolidated list of PT 21 technical agreements". The WG agreed that the PT 21 technical agreements should not be changed concerning the correction factor.

Action: The above conclusions will be reflected in the next **TAB** version.

Post-WG meeting note: During the WG meeting, reference was made to TAB v1.4. Since this version is already under commenting by the APCP WG and SECR would not like to delay the publication, the ENV part will be updated in the next version 1.5 (together with TOX and EFF), scheduled to be ready for commenting in December 2017.

8.5 Applicability of the AHEE recommendation for PT 18 to PT 3 (ECHA)

The SECR presented the outcome of the e-consultation which took place after the WGIII2017 to clarify applicability of the "Addendum to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems, ENV/JM/MONO(2006)4" (2015) to PT3 uses. Since the WG members were of the view that the Addendum cannot be applied to PT3 in full (question 1 of the e-consultation), the following specific questions were further addressed in the discussion at WGIV2017:

2. Does the WG agree with the proposal to change Tmanure-int$_{ar2}$ from 212 to 365 days in the additional scenario for arable land in case of PT 3?

The WG agreed to follow option B (alternative proposal by DE as discussed in the 1st PT 18 EG meeting), i. e. Tmanure-int$_{ar2}$ (manure storage time arable land in new scenario) should be derived from applicant's data as a period between two subsequent insecticide treatments in the animal housing assuming that Tar-int will be equal to Tbioc-int.

3. Does the WG agree that the Nlapp-grass of 4 can be kept in case of PT 3?

The WG confirmed the conclusion of the e-consultation Nlapp-grass (number of land applications for grassland per year) of 4 is equally relevant for PT 18 as well as PT 3.

4. Does WG agree that the calculations for the maximum number of insecticide applications during manure storage period of manure to be spread on grassland Napp-manure$_{gr}$ as presented in section 2.3.3 of the Addendum (2015) should be adopted for the PT 3 uses as such?

The WG agreed to use the same approach to be agreed for PT 18 (open point from item 8.2 of the WGIV2017 meeting agenda) also to PT 3.

5. Should the land application interval for grassland Tgr-int of 53 days be used for PT3 or is 91 days more appropriate (even distribution throughout the year)?

The WG agreed that the land application interval for grassland Tgr-int of 53 days can be adopted for PT 3 uses.

6. Does WG agree that sections 3.2-3.6 of the Addendum (2015) are applicable to PT 3 without changes? (pending the decision on the land application interval for grassland Tgr-int under point #5 above)?

The WG agreed to use the same approach to be agreed for PT 18 (open point from item 8.2, point 1 of the WG-IV-2017 meeting agenda) also to PT 3.

Action:

- DE to replace "-" by underline in the equations presented under the last point (item 6).
- **TAB** entry on the proposed conclusions.

8.6 Definition of relevant impurities (ECHA)

SECR gave a brief introduction to the agenda item. The main arguments from the e-consultation after WG-III-2017 were presented and the next steps in the process were explained. In addition, reflections from the discussion at the TOX WG-IV-2017 meeting as

well as feedback from EFSA were reported. The ENV WG members were invited to give further comments on the Option 1 and Option 2. DK and FR confirmed that they have no further arguments to add to the comments that were submitted in the e-consultation.

Action: SECR will continue to work on this item based on the feedback collected from the ENV and TOX WG as well as from the consultation with EFSA. The SECR proposal is planned to be provided in the context of the first draft of the revised technical equivalence guidance.

8.7 Specific items identified in the revision of Vol. IV Part B for WG follow up (ECHA)

The SECR presented two documents under this agenda point: a) on triggers for sediment risk assessment for biocides and b) on relevance of food vs water exposure in sediment toxicity testing. The documents contain proposals for revision of the BPR Guidance Vol. IV Part B which were taken out from the first revision for further development by the WG. The WG members were invited to provide initial comments at the meeting, noting that e-consultation would be launched for both documents after the meeting.

With regard to the document on triggers for sediment risk assessment, DE mentioned that their main concern with regard to the new scheme is that although the triggers for sediment assessment have better reasoning, the screening steps are still based on old triggers and therefore it will not provide any further insight on the sediment. The main consequence is that effect testing data is required to use the triggers and the additional AF 10 for substances with high Kow would not be justified. NL highlighted that in the decision scheme provided in the document, some qualitative conditions are provided which could cause problems with interpretation. NL also asked for clarification on whether the condition of PEC being calculated with EMP is correct.

On the subject of the relevance of food vs water exposure in sediment toxicity testing, NL questioned the need for two 10-day studies instead of one chronic study with contaminated food. DE was of the view that the two 10-day studies with limited number of test concentrations would be simpler and cheaper than the full chronic study. The Chair noted that it would involve the Swiss Centre for Applied Ecotoxicology in the subsequent e-consultation. CEFIC suggested that it would be also valuable if someone who has experience with OECD 218 test.

Action: SECR to launch an e-consultation on the two topics.

8.8 Ongoing developments related to PT 21 (NL, UK)

a) Update on the development of harmonised scenarios for freshwater: pleasure craft and commercial ships (NL)

At WG-III-2017 a document was presented that described the analysis of the freshwater marina data submitted by the participating MS, using two dummy substances and including the outcomes of two existing regulatory scenarios. The analysis followed a similar methodology as that employed for the saltwater marinas by the UK CA, ultimately producing a distribution of PEC values inside and outside a series of marinas, from which percentile PECs can be drawn. Two types of zero PEC outcomes were reported in the analysis presented at WG-III-2017. One zero outcome type could be repaired by submission of new data for the suspended matter concentration in some marinas in the German data set. The other zero outcome seemed to be caused by a bug or boundary setting in the MAMPEC software. The MAMPEC developers are looking for possibilities to repair this issue. The four marinas showing the latter type of zero output were taken out of the freshwater marina data set. Due to these alterations in the data set, the analysis presented at WG-III-2017 had to be redone and the revised version was presented at WG-IV-2017. The WG IV version of the document corresponds with the PEC calculator tools that were subsequently developed. These Excel tools were kept equal -as much as possible- in design and functioning to the PEC calculator tools for the saltwater marinas. The freshwater Excel tools were cross-checked for input of the PEC concentrations generated

by MAMPEC runs, by the MS that assisted in the development. After finalisation the Excel tools were sent to ECHA where they were part of a written consultation period. The tools will be made available via ECHAs website, together with the revised version of the PT 21 product authorisation manual and the saltwater PEC calculator tools, both prepared by the UK CA.

b) Update on the situation for marine waters/marinas (UK)

Over summer 2017 the UK received substantial support from several MS (NL, DE, FI, DK, SE, FR) preparing MAMPEC simulation data necessary to develop the environmental risk assessment tools for PT21 substances. The development of these tools was supported by earlier consultation with the CA meeting in March 2017. The UK used these data to create substance specific Excel calculation sheets and also updated the associated PT21 Products Authorisation Manual guidance (first discussed at AHEE-1 physical meeting). The manual and calculation sheets were sent out for final consultation at the end of July, with comments received by several MS by the deadline of 11 August 2017. Subsequently the UK has been finalising the tools and guidance in preparation for publication on the ECHA website. The only outstanding technical issue relates to the choice of wet surface area – the tools will be updated to reflect the outcome of the separate e-consultation on this (closed 15th September) and final versions will be sent to ECHA by the end of September.

9. AOB

9.1 Other information & lessons learned

The following "**Other information**" was provided:

Guidance repository: New guidance does not apply immediately (different agreements of the CA meeting and of the BPC). During the transitional period, it is necessary to refer to previous versions of the guidance. A new web page is to be created for replaced/updated guidance, the link to this page will be included in the BPR Guidance page. It is expected to be available in October 2017.

Transitional guidance: Transitional guidance developed under BPD has been kept at the ECHA website until new (ECHA) documents are available. The site will be closed when Vol IV is published in September 2017.

ED criteria: For pesticides, there was a vote in favour of COM proposal in SC PAFF on 4 July; for biocides, agreement at CA meeting on delegated act on 12 July.

Adoption process involving EP and Council: ED criteria may enter into force by the end 2017, application date 6 months after entry into force.

ED guidance and implementation: Hazard identification guidance development by ECHA and EFSA. Draft prepared by ECHA and EFSA sent to Consultation Group, ED EG + MSCA pesticide experts selected by EFSA + registered stakeholders (deadline end of August). Commission notes on implementation of scientific criteria to determine endocrine-disrupting properties of a) active substances currently under assessment (on-going evaluations) and b) biocidal products, discussions at July & September CA meetings.

ED criteria – consequences: pending on positive outcome at EP & Council, discussion on COM proposals at September Biocides CA meeting. Note on implementation of scientific criteria to determine endocrine-disrupting properties of active substances currently under assessment (on-going evaluations).

The following consequences may be expected:

- COM will return to ECHA the BPC opinions adopted in several future meetings, requesting an ED assessment based on the new criteria - this assessment will have to be carried out by the eCA.

- CARs submitted by the eCA by 2 October 2017 (Process Flow 22): the ED assessment has to be based on the interim criteria, the BPC opinion is finalised but will be returned by COM.
- CARs submitted by 22 January 2018 (Process Flow 23): the ED assessment has to be based on the new ED criteria, CARs without assessment based on the new ED criteria will fail the accordance check.

Feedback on ENV WG related items discussed at BPC-21: UA-APP - higher tier groundwater assessment: "*The BPC confirmed the conclusion of the ENV WG, that all nine FOCUS scenario should show a safe use, since a product authorised by Union Authorisation can be placed on the market in all Member States. However, if this is not the case and the applicability of the models for the substance evaluated can be questioned, a qualitative approach could be applied using expert judgement in a weight of evidence approach".*

Remaining items to be discussed at BPC-22 (October 2017): Remits of the ENV WG when discussing RMM, new endpoints after AS approval triggering an update of the LoEP.

In addition, two items are forwarded to September CA meeting**:** BPR Annex VI, Art 68: Relevant metabolites in groundwater, BPR Annex VI, Art 69: Comparison of $PEC_{surfacewater}$ with limits of 98/83/EC.

ESD spreadsheets – state of play:
- **PT 8** and **PT 13** – final draft sent out to the commenting MS on 5 Sept. Publication foreseen in Oct 2017.
- Previously circulated spreadsheets:
  PT 9 rubber: commented twice by the MS; to be published soon.
  PT 10: commented once by the MS; comments were implemented but a couple of issues still need to be clarified with the AHEE/WG; the spreadsheet will be be circulated once more for confirmation before publishing.
- **PT 11**, **12** and **PT 18 households, PT 18 animal housing** and **PT 18 manure storage** – in preparation
- **PT 3** and **PT 6** to be started as soon as possible
- Update of published spreadsheets is also priority (e.g. alignment with new TAB entries)

General items: The functional mailbox "AHEE" will be renamed into "Environment".
SECR asked if there are any emission estimation related items pending that need clarification/harmonisation? They should be upload with a "thought starter" document in the dedicated AHEE Newsgroup and inform SECR. Deadline: 30 November 2017, discussion/agreement at WG-I-2018.

Next WG meetings: ENV session of **WG-V-2017** provisionally planned for 22-24 November (Wednesday - Friday). The focus on active substances, only limited guidance related items will be discussed.
The ENV session of **UA-PF 20 WG meeting** provisionally planned for 4 or 5 December (Monday or Tuesday) as virtual meeting.
The ENV session of **WG-I-2018** provisionally planned for 24-25 January, most likely as physical meeting. Deadline to provide guidance related documents for discussion/agreement: 12 January 2018 (deadline for AS related documents: 15 December 2017 according to the timelines for AS approval).

The following "**Lessons learned**" were shared:

Problems in reference specifications: The reference specification is a key element of the assessment and should be the starting point. There are several examples of substances with complications due to problems in the reference specification. MS were invited not to submit a CAR before the reference specification is clear.

General items: In case of new exposure assessment approaches or changes in scenarios/default values use the possibility of early WG meetings. The conclusions of the

WG should be reflected in the (updated) CAR: if eCA deviates from the WG conclusions, this needs to be agreed by the WG!

eCAs were invited to inform SECR, if they cannot keep timeline for commenting the DT – this is to prevent repeated uploading/ creation of multiple versions.

9.2 Revised PBT guidance

Due to time constraints the item was moved to WG-V-2017.

ENV WG Appendix 1:

Agenda item 8.1: Update on guidance development, issues to be sent to the AHEE

Note:

- Issues unchanged since WG-III-2017 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**	The PT 21 PA manual prepared by UK was endorsed at WG-I-2017, some items were forwarded to the 70th CA meeting. A written procedure on wet surface area of recreational boats was initiated with a deadline for providing comments of 15th September 2017. NL will present the freshwater scenarios for confirmation at the September CA meeting. **NL/UK presented the status at WG-IV-2017. An e-consultation was initiated concerning the wet surface are of recreational boats with a deadline for providing comments of 15th September 2017**
1.2	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[2] 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.
1.3	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 (=> potentially in 2018)**.
1.4	1st revision of Vol. IV Part B (active substance) + new biocidal product part including SoC) (**ECHA**)	1st revision: First update to Part B (active substances) to address outstanding issues from publication of version 1.0 + update to add risk assessment of biocidal products and Annex for Substances of Concern (SoC) and to add Part C Evaluation to create joint document "Assessment and Evaluation (Parts B+C). • CA consultation closed – no comments received • Publication is foreseen for September/October 2017

[2] **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
		An update on the status/further steps was provided at WG-IV-2017.
1.5	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. Documents were provided by DE to ECHA, SECR initiated e-consultation after the WG meeting. **Document planned for a final discussion at WG-I-2018 (TBC by DE).**
1.6	TAB (**ECHA**): Technical Agreements on Biocides	Version 1.3 was published on the ECHA webpage, items for the next version TAB v1.4 will be discussed at WG-IV-2017. **Correction post WG meeting**: The agreed items at WG-IV-2017 will be included in TAB v.1.5 since version 1.4 (containing updates of the APCP part) is already at MS commenting stage. **TAB v1.5 is scheduled to be distributed for commenting end of Q4 2017.**
1.7	ESD for PT 6 (**DE**)	DE has revised the ESD following comments received. **The ESD was endorsed at WG-I-2017, DE provided the draft final version to SECR, final check is ongoing together with DE.**
1.8	Evaluation of ESD PT 14 (**DE**)	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. **First discussion planned at WG-V-2017. A commenting round was started on 11th September 2017 with ad deadline for providing comments of 13th October 2017.**
1.9	Manual of instructions to eCAs for evaluation of active substances used in disinfectants	The final version has been provided by the consultant; finalised by SECR in August 2017. Publication expected during September 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?	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 and was forwarded to the 70th CA Meeting, where the collection of tonnage data was not agreed.

No.	Title (current leader)	Status
	⇨ *WG-I-2015 – item 6.2 + WG-II-2015 – item 7.3 WG-II-2014 – item 6.4 (pulp and paper processing fluids)*	**A summary of the agreed times will be prepared by SECR and provided for information to the ENV WG at WG-I-2018.**
~~2.2~~	~~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.~~ ~~**The item was discussed and agreed at WG-III-2017, the final document was included in TAB v1.3.**~~
2.3	PT 3: Scenario for disinfection in aquaculture ⇨ *Disinfection project/EMA visit*	ECHA contracted out the preparation of a first proposal. First discussion took place at WG-I-2017, comments received during the commenting period to be added. **Revised version will be provided for discussion/agreement at WG-I-2018.**
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	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. *Following feedback from FR, this item is no longer relevant since covered by the substance specific Excel Sheets developed by UK/NL for marine and freshwater marinas.*
2.6	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.
2.7	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? ⇨ *WG-V-2016 – item 6.1*	**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)		
2.8	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.
2.9	PT 8: Use of a standard transfer factor (38 or 40) for transferring an application rate	*Item was solved in the frame of item 8.3 of the WG-IV-2017, therefore no longer relevant (a factor of 40 was agreed).*

No.	Title (current leader)	Status
	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 6.3*	
2.10	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. *This item may by send to the ENV WG for an early WG meeting discussion in the frame of an UA case.*
2.11	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.
2.12	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.
2.13	Refinement options for PT 11 once through and large recirculating systems ⇒ *WG-II-2016 – item 6.8/6.9*	AHEE member to take over item to be assigned – document form industry awaited.
2.14	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.
2.15	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.
2.16	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.
2.17	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.

No.	Title (current leader)	Status
2.18	PT 10: Removal processes ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.19	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.
2.20	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.
2.21	PT 19: review of default value for Fsim (worst case to apply the Fsim of PT 18 to PT 19?) ⇨ *BPC-19 – AP 07.05*	AHEE member to take over item to be assigned.
2.22	Development of guidance for bees and non-target arthropods ⇨ *CG (2017)*	AHEE member to take over item to be assigned. *Note: DE and CH have initiated national projects to collect information which could be the basis for a future guidance document.*

ENV WG Appendix 2: Item 8.3 - Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19

The following conclusions of the ENV WG will be reflected in **TAB v1.5**.

Post meeting notes:

EWPM provided comments on the conclusions after the WG meeting. They were shared with the ENV WG and added to the respective items in the DT as post WG meeting note for transparency reasons and for information.

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19			Meeting date: 12-14 September 2017
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
1.	City scenario – calculation of number of houses in which the product is expected during application (indoor applications) Follow up action from WG-II-2017 (SECR/NL) The city scenario indicates how to determine the number of houses in which the product is applied on a single day. For the particular case of indoor applications $N_{house,application}$ is indicated to be **one** for certain products (see yellow highlighted sentence in the Background section). As the emissions during service life are calculated using N_{house} = 4000 and $T_{service}$ = 3650 d, this leads to a theoretical value of $N_{house,application}$ = 1.1. This means that the calculation leads to a service life emission of more active substance than has been used during application. Upon bilateral consultation, NL indicated that $N_{house,application}$ should be calculated by the formula below and the result should be rounded up:	**Point closed.** The WG agreed to the proposed equation and the rounding up as well as to the delete the sentence (highlighted in yellow) in the background section in the city scenario. According to the equations in the city scenario, the factor fhouse should be added in the nominator of the equation provided in column b).	

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19			Meeting date: 12-14 September 2017
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
	$$n_{house,application} = \frac{n_{house,city}}{service\ life * 365}$$ Where: $N_{house,\ application}$ = number of houses in which the product is applied on a single day (-) $N_{house,\ city}$ = number of houses in a city (4000) Service life = service life of the preserved products (year) 365 = number of days in a year In case of a service life of 10 years, the number of houses that are treated daily is 1.1 rounded up to the nearest integer, i.e. 2 houses per day instead of 1 or 1.1. **To be discussed:** Should the number of houses from which emission is expected during application ($N_{house,application}$) <u>always</u> be calculated by using the above formula? If so, should the sentence in the city scenario document, which is highlighted in the Background section, be deleted?		
	Background At WG-III-2017, the question came up whether the city scenario would need to be revised. The eCA used the city scenario to estimate the emissions of the substance in sealants and grouts from indoor application and from leaching during service life. For application, the eCA used Nhouse.applic = 1 per day (according to the last paragraph before the "References" section in the city scenario document*****), while emissions during service life have been calculated using Nhouse = 4000 and Tservice = 3650 d (which leads to a theoretical value of Nhouse.applic = 1.1). This means that the calculation leads to a service life emission of more active substance than has been used during application. *****<u>For the particular case of **indoor** applications, the **city scenario** indicates that:</u> "The number of houses treated daily depends on the service life of the product. For paints and joint sealants having a service life of 5 years 800 houses are treated annually when assuming that the product is applied on 100% of the houses in a city. Although this may suggest that 2.2 houses are painted daily, Nhouse,applic have to be three houses per day to compensate for days that are not suitable for painting because of the temperature and/or precipitation. For all other products Nhouse, applic is one."		

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19			Meeting date: 12-14 September 2017
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
2.	<u>Use of PT 8 scenario for outdoor spray application in PT 6, 7, 9 and 10</u> ESD Spreadsheets preparation (SECR) TAB ENV 100 (v1.3) mentions that "For the assessment of "spraying" application in PT 10 and similar applications in other PTs (e.g. PT 6, PT 7), the scenario provided for outdoor in-situ spraying in the OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 2 - Revised Emission Scenario Document for Wood Preservatives (2013), chapter 4.4.5, should be used also." In addition, in the conclusions for Folpet (PT 6, 7, 9) discussed at WG-I-2014 is stated, "The spray application should be calculated using the scenario and default values provided in the revised OECD ESD for PT 8 for in-situ outdoor spraying." The PT 8 scenario for in-situ outdoor spray application considers that the assumptions regarding wind speed conditions in PT 10 are not correct. **To be discussed:** 1. Should the PT 8 scenario for outdoor in-situ spraying replace the PT 10 scenario for spray application or should it be added to PT 10? a. If replaced, should the approach in PT 10 be kept, i.e., define emission scenario for calculating releases from roof and emission scenario for façade, or just emission scenario for calculating releases from façade as in the ESD for PT 8? b. If added, what should be the criteria to decide which scenario to use? Is it sufficient that for approval in spraying application use one of the scenarios leads to safe use? 2. Should the PT 8 scenario for spray application be added to PT 6 and to PT 7?	**Ad 1:** **Point provisionally closed** but Action in column e) to be followed up. The WG agreed to the replace the scenario for release to soil in the countryside in PT 10 by the scenario for PT 8 (in situ outdoor spraying). For the application phase for PT 6, 7, and 10 in urban areas covering the area around the house during treatemnet should be in line with the tiered approach for PT 8. For service life, the city scenario remains valid for PT 10 for release in urban areas. Concerning the consideration of the roof area, the roof should be included in the in-situ outdoor spraying scenario according to PT 8 but be used only on a case by case basis if relevant. **Ad 2: Point closed.** The WG agreed to use the scenario for PT 8 also as first	**Action Ad 1:** SECR to prepare a proposal and to share with WG (check if extension to roof with the proposed parameterisation in the ESD for PT 8 is feasible)

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19			Meeting date: 12-14 September 2017
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
		tier for PT 2 (algicide), PT 6 and PT 7. The first tier can be revised (e.g. default values for Fdrift and Frun-off) based on further information provided in the frame of concrete cases.	
3.	<u>PT 8 – UC 3 – Use of laboratory study data</u> Dedicated Newsgroup until 10 March 2017 – PT 8, Item 1 (UK) UK noted the lack of guidance on how to interpret UC 3 laboratory study data for intermittent wetting of treated wood. Furthermore, UK notes that existing guidance on kinetic modelling only addresses continuous immersion. UK questions how can MS ensure consistency in approach and generate robust leaching rates / cumulative emissions. **To be discussed:** WG members are invited to share their own approach to generate leaching rates/cumulative emissions.	*No conclusion (open/closed) needed.* NL and DE to provide a description of their approaches as presented at the meeting to SECR, SECR to include them in the minutes.	**Action**: **NL** and **DE** to provide the respective description. **SECR**: A need for guidance on how to interprete leaching studies and on how to calculate the leaching rate was indentified. This could be solved potentially in a workshop. Organisation of such a workshop is so far open.
4.	<u>PT 8 – UC 4 – Guidance on groundwater assessment</u> Dedicated Newsgroup until 10 March 2017 – PT 8, Item 2 (UK) UK pointed out the lack of harmonised guidance on groundwater assessment for UC 4 scenarios (both soil and groundwater are flagged up for consideration with regard to transmission poles and fence posts). UK notes that a number of issues are identified why groundwater determination would be difficult but no assistance is given in relation to	**Point closed.** The WG agreed to use the scenario for railway sleepers as a first tier to assess the groundwater comprtment for UC4.	

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19		Meeting date: 12-14 September 2017	
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
	dealing with these issues or likely area of wood per hectare. **To be discussed:** Do the WG members consider necessary to develop guidance on groundwater assessment for UC 4? What is the WG members experience with the groundwater assessment for UC 4?		
	Background: Additional information from UK: The UK CA has had concerns with the lack of guidance in the PT 8 ESD in relation to groundwater assessment for UC 4a timber - whilst leaching loss from above ground and below ground is described by equations, there is the problem that a fence post is considered to be buried to 1 m and a transmission pole is buried to 1.5 m, especially when the aquifer is fixed at a depth of only 1 m. How do we realistically assess concentrations reaching groundwater in a harmonised way? A 2-tier approach separating above ground and below ground losses could be applied so that losses above ground would fall onto soil surface and be modelled as usual in PEARL. However, below ground losses would be at a depth of 1 cm – 100 cm for post and 1 cm – 150 cm for pole and we are not clear how that could be easily and reliably modelled for migration / degradation in soil. Furthermore, how would the above & below ground values be combined for a cumulative GW concentration? In addition, there is no guidance available on how to predict likely numbers of poles / posts per hectare as calculations as FOCUS PEARL traditionally relies upon dosages in kg/ha. In order to complete national lead product evaluations, we have estimated values for the UK based upon limited information from utility companies and scientific reasoning but do not know how reliable they will be to other MS.		
5.	<u>PT 8 – Interpretation of semi-field leaching studies</u> Dedicated Newsgroup until 10 March 2017 – PT 8, Item 3 (UK) UK proposes to discuss the harmonisation of the approach taken for interpretation of semi-field leaching studies, particularly on the calculation of cumulative leaching at Time 2 (and how to extrapolate beyond 1 – 2 years to achieve this in a robust manner). **To be discussed:** The WG members are invited to share how they interpret semi-field	*No conclusion (open/closed) needed.* NL, DE, UK and DK to provide their way of calculation to SECR, SECR to include in the minutes and share with UK. A general overview on how to interpret leaching studies is provided in the minutes of the	**Action**: **NL, DE, UK** and **DK** to provide their way of calculation to SECR **SECR**: Refer to item 3 above (to be included in a potential workshop).

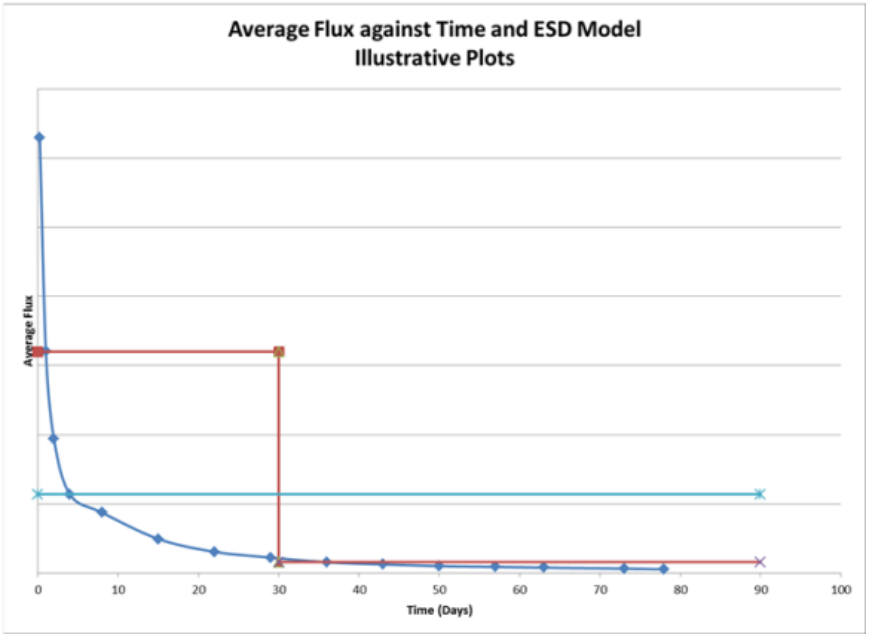
Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19		Meeting date: 12-14 September 2017	
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
	leaching studies, how they calculate the cumulative leaching at Time 2 and how extrapolate beyond 1 – 2 years.	2nd EU leaching workshop. UK to compare different calculations and provide conclusions (as far as possible). Focus is specifically on the question how to deal with cases where no plateau was reached (DK noted that a leaching test should be continued until a plateau is reached).	
6.	<u>PT 8 – Risk assessment</u> Request by UK CA for help on Time 1 issues in PT 8 (email 06.06.2017) (UK, DK) UK questions how to deal with products in PT 8, UC 3 and above, when a risk is identified at TIME 1 (even by a small exceedance of the trigger value of 1) but TIME 2 can be shown as acceptable; should it be assumed that reasonable RMMs have been considered but there is a risk at 30 d? DK noted that at the 2nd EU Leaching Workshop there were suggestions that risk should be calculated for 1 year if unacceptable risk was identified at 30 days and noted that for UC4 a risk for 30 days cannot be avoided. ECHA would collect data and evaluate if there is a change in the outcome of the short time risk (30 days and 1 year). *SECR: A validation step of the new Time 2 was agreed by the CA meeting. For this, a Newsgroup was added at S-CIRCABC to collect calculations on Time 2 (365 d) to be provided by eCAs. ECHA to perform*	*No conclusion (open/closed) needed. Policy related issue, not in the remit of the ENV WG to conclude.* This point was not concluded since awaiting the outcome of the validation of the new Time 2. Proposal of NL to be added to the minutes. A recommendation was to apply pending the impact assessment the same approach as agreed for active substances (acceptable if Time 2 is safe). However this	

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19		Meeting date: 12-14 September 2017	
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
	the impact assessment as soon as sufficient information is available. **To be discussed:** The WG members are invited to share their views on this issue.	approach was not agreed in general in the frame of the 2nd EU Leaching workshop.	
7.	<u>PT 8 – Risk assessment</u> Request by UK CA for help on Time 1 issues in PT 8 (email 06.06.2017) (UK, DK) UK questions whether any tolerance could be applied on the grounds that models are over-protective when PEC/PNEC = 1.05 (for example). UK questions whether such PEC/PNEC would be too high to allow more than UC 1 and UC 2? Note that the value of 1.05 is chosen as anything smaller could be rounded down to 1.0 as two significant figures. UK acknowledges that inclusion of an intermediate assessment period of 365 d may clarify the decision making process in the future but notes that positions for authorisation of specific products need to be made long before the impact assessment for that concept will be completed. See also in the Background section, the document prepared by UK with the outcome of the e-consultation to CAs in DE, NL, FR and SE. **To be discussed:** The WG members are invited to share their views on this issue.	*No conclusion (open/closed) needed. Policy related issue, not in the remit of the ENV WG to conclude.* The recommendation of one WG member was to further refine the exposure assessment. SECR noted that this item is rather an issue for regulators (how to deal with cases when the PNEC/PNEC is exceeded).	
	Background: Document provided by UK with the outcome of the e-consultation on TIME 1 issues in PT 8:  Outcome e-consult_Tier 1 for I		

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19		Meeting date: 12-14 September 2017	
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
8.	<u>PT 8 – Risk assessment</u> Request by UK CA for help on Time 1 issues in PT 8 (email 06.06.2017) (UK, DK) UK questions what reason is given to prevent authorisation if a PEC/PNEC >1 at TIME1 cannot be accepted for UC 3 and above? UK highlights that specific mention of any relevant BPR Article used successfully by an MS or reference to other legal decisions (i.e. Commission Decisions) would be very helpful to them. DK suggests as a way out that the use could be limited to windows and doorframes. **To be discussed:** The WG members are invited to share their views on this issue.	*No conclusion (open/closed) needed. Policy related issue, not in the remit of the ENV WG to conclude.* NL comment to be included in the minutes WG members noted that it would not possible to grant a national authorisation if the PEC/PNEC is above 1. DK to share their scenario on treatment of windows and doorframes. SECR to include into the minutes.	
9.	<u>PT8 – Use Class 4b - Jetty in a lake and a sheet piling in a small stream or waterway scenarios</u> ESD Spreadsheets preparation (DK email to SECR 30.06.2017) (DK) When assessing the environmental exposure from wood in use class 4b, the ESD states the following: "*For Use Class 4b, two scenarios are considered: a jetty in a lake and a sheet piling in a small stream or waterway. The jetty scenario is a worst case with respect to the wood surface area, whereas the sheet pilings scenario represents a worst case because of the wood being exposed mainly under water.*" DK questions whether both scenarios should be calculated and acceptable risks should be shown for both scenarios in a product evaluation? Further, both scenarios are not relevant in all Member States, e.g. sheet piling in	*No conclusion (open/closed) needed. Policy related issue, not in the remit of the ENV WG to conclude.* WG members recommended that both scenarios should be safe (this would be mandatory for UA). FR noted that it would be sufficient to calculated only the worst case of both sceanrios. There should be flexibility on national authorisation level in	

a) No.	b) Issue and background Ref. in RCOM	c) Open/closed point Conclusions	d) Action points Deadlines
	a waterway is not a relevant scenario for Denmark, but the Jetty in the lake is. **To be discussed:** Would it be acceptable to do a use-specific assessment, where acceptable risk shown for the relevant scenario, thus e.g. limiting the use of the product to non-flowing water?	case in a specific MS the situation reflected in one of the scenario is not relevant.	
10.	<u>PT 8 – Treated wood in service UC 3 – 4 – definition of TIME1, TIME2 and TIME3</u> ESD Spreadsheets preparation (DK, FR, NL, RCOM PT 8 & 13 #44, #45, #46) IND email (Applicant email to SECR, May 2017) Several members raised issues on the way TIME2 and TIME3 are defined and consequently how the cumulative quantity of substance leached out of 1 m2 of treated wood over the intermediate / longer assessment period is to be calculated. DK considers that the first 30 days should be subtracted from the longer assessment period when leaching data are used. Also NL is of the opinion that the leaching rates should be based over the period 30-TIME2 and TIME2-TIME3. The applicant notes that the current 2 time points in the ESD are considered as two time windows: during the first 30 days of the service life and during the rest of the service life (>30 days) (p.24, 68). Furthermore, an applicant indicates, *"for substances that degrade (assuming say DT50 of 500 days) the amount emitted in the first 30 days will be negligible at the 7300 day point and can effectively be ignored for the time 2 risk. For substances that do not degrade we add the risk for both time points together."* (See also Background section) Furthermore NL questions which value should be used for the final	**Point provisionally closed.** The WG agreed in priniciple to a tiered approach using the method as described in the ESD (cumulative leaching from day 1 – end of service life) as a fierst tier and the "refined" method using the different leaching rates for the time spans between Time 1 – Time 2 – Time 3 for the calcualtions. The refined method needs further clarification and agreement, NL will share their calculation sheet with an explanatory note first with FR and DK (to cross-check) and then with the WG for final agreement (ASOs to be included for information).	**Action: NL** to provide their Excel sheet with an explanatory note. **FR** and **DK** to cross-check. **ENV WG** to finally agree.

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19			Meeting date: 12-14 September 2017
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
	decision: Qleach1 which is only valid for freshly impregnated wood, Qleach2 that is the emission over one year, or Qleach3 for the whole service life? SECR refers to the document "Summary: Conclusions of the 2nd EU Leaching Workshop on Wood Preservatives" (TAB ENV 90, v1.3): in case leaching data is available: TIME 1: from day 1 to day 30 TIME 2: from day 1 to day 365 TIME 3: from day 1 to day n (n depends on the application method/process) (that is, point 2 - Step 3 applies) Also in Appendix 2 of ESD for PT 8, Table A2_1 (p.154) an example of cumulative quantities are given for time intervals that always start on day 1, e.g., 1-365 days, 1-3653 days. **To be discussed:** How should TIME2 and TIME3 be calculated?		
	Background: Comment from an applicant: "[…] In calculating emissions we have taken the average daily rate over 0-30 days and then 30-7300 days for a 20 year service life. For substances that degrade (assuming say DT50 of 500 days), the amount emitted in the first 30 days will be negligible at the 7300 day point and can effectively be ignored for the time 2 risk. For substances that do not degrade, we add the risk for both time points together. However, an alternate approach for time 2 would be to take the average over 0-7300 days. This will always give a higher value for time 2 as influenced by the larger short-term loss over 30 days, as shown below. The ESD effectively works as a stepped function and emission rates will always exceed the actual rate at 7300 days and is worst case. By using emission rates determined over 0-7300 days it is significantly worse, especially for degrading substances.		

a) No.	b) Issue and background Ref. in RCOM	c) Open/closed point Conclusions	d) Action points Deadlines
	 It is not so much whether 7270 or 7300 days is used as the time 2 window in the risk calculation but how the time 2 leach value is derived. […]"		
11.	<u>PT 8 – Treated wood in service UC 3 – 4 – Vsed default value for bridge over pond scenario and jetty in a lake scenario</u> ESD Spreadsheets preparation (FR, UK, NL, RCOM PT 8 & 13 #47, #48, #49) FR and UK noted that the parameter **Vsed** should have the following default values, as agreed for the Granulated copper, PT 8 CAR (Jan 2016):	**Point closed.** Related to chatper 3 of the OECD ESD for PT 8 (3.18/19): The WG confirmed that that the already agreed values should be added ot the TAB. Note that the Vsed is not used to calculated the PEC sed, it is	

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19		Meeting date: 12-14 September 2017	
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
	i) For bridge over pond scenario (treated wood in service UC 3) – **Vsed = 3 m^3**, based on a 3 mm sediment layer and a pond surface area of 1000 m^2 ii) For jetty in a lake scenario (treated wood in service UC 4b) – **Vsed = 23.56 m^3**, based on a 3 mm sediment layer and a diameter of 100 m. **To be discussed:** Should the following default values for **Vsed** be added in the TAB: i) 3 m^3 for bridge over pond scenario and ii) 23.56 m^3 for jetty in a lake scenario	used to take into account dissipation from the water layer in order to refine the PECsw. It was further noted that WG members use as a standard rather equations 3.16/17.	
12.	<u>PT 8 – ESD – guidance harmonisation regarding sorption to sediment</u> ESD Spreadsheets preparation (NL, RCOM PT 8 & 13 #49) NL notes that the ESD is not harmonised with the guidance regarding sorption to sediment as the latter assumes (deposited) suspended mater. NL therefore proposes to replace RHOsed, Vsed and Ksed-water by RHOsusp, Vsusp and Ksusp-water, which is not only according to the guideline, but makes it also possible to apply formula 50 (guidance) to calculate PECsed. Furthermore, NL indicates to have already applied the described approach for their (EU) product authorisations. **To be discussed:** Do the WG members agree with the proposal by NL to replace RHOsed, Vsed and Ksed-water by RHOsusp, Vsusp and Ksusp-water, as described above?	**Point open.** Follow up group (see actions) to check the implication of the change of taking into account the default values for suspended matter instead of the default values for sediment (as reflected in eq 50 in Vol. IV part B). Item related to eq. 3.18/19 in the OECD ESD for PT 8.	**Action**: **NL, DK** and **FR** to follow up the item. **CEFIC** to provide their comments to SECR
13.	<u>PT 8 – Treated wood in service UC 3, UC 4b – Surface water considering removal process</u> ESD Spreadsheets preparation (DK, FR, UK, RCOM PT 8 & 13 #52, #53)	**Point open.** To be followed up, see column e)	**Action: WG** members to provide a short description of their

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19			Meeting date: 12-14 September 2017
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
	FR notes that the equations 3.16 and 3.17 provided in the ESD (p.31) to calculate the time weighted concentration in local water over an initial/longer assessment period, to take into account removal processes, already consider adsorption to suspended matter. FR points out that the **k** that should be used for surface water calculations (first order rate constant for removal from water) takes into account degradation and dissipation. However the ESD indicates that to take into account removal due to adsorption onto suspended matter and into sediment equations 3.18 and 3.19 (p.32) should be used. These equations require the use of $\mathbf{K_{sed\text{-}water}}$ (total sediment-water partitioning coefficient) and $\mathbf{Kp_{susp}}$ (solids-water partitioning coefficient for suspended matter), in addition to **k** above. FR considers that these equations (3.18 and 3.19) take into account the adsorption of suspended matter twice. The SECR proposed the following way forward: • DT50 from a degradation test in water: Take equations 3.18 + 3.19 into account (ESD PT 8, p.32) in addition to equations 3.16 + 3.17 for further refinement (ESD PT 8, p.31). • DT50 from a water/sediment test: Do not take into account above equations (3.18 + 3.19), since distribution to sediment (i.e. dissipation in water) is already measured in the test. FR, DK and UK also highlighted the need for calculations for PEC sediment for these scenarios (also related to Item 14 below). **To be discussed:** 1. Do the WG members agree with FR and are the equations 3.18 and 3.19 regularly applied in practice? 2. Do the WG members agree with SECR's proposed way forward		calculation, SECR to compare. **SECR** to open **Newsgroup** for this agenda item

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19		Meeting date: 12-14 September 2017	
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
	regarding the PEC surface water? 3. Regarding PEC sediment, is this usually calculated for PT 8 using EPM?		
14.	<u>PT 8 – calculation of sediment concentrations</u> ESD Spreadsheets preparation (DK email to SECR 30.06.2017) (DK) The DK CA noted that there is no suggestion for how sediment concentrations are calculated in the ESD for PT 8 , e.g. for use class 3 and 4b. As different approaches could be applied the DK CA proposes to agree on a common approach that can be included in the ESD excel sheet (further information is provided in the Background section). **To be discussed:** Approach to calculate sediment concentrations.	See conclusion of previous item	**Action**: to be included in the follow up agreed for the previous item
	Background: Additional information from DK: According to the ESD for PT 8, the removal of active substance by adsorption onto suspended matter and into soil from the water column can be taken into consideration by using table 3.8 on page 32 (for static water bodies) and table 3.8 on page 34 (for flowing water bodies). These have been included in the calculation sheets for PT 8 provided by ECHA. In the Guidance on the BPR (Volume IV Part B) on page 79 a thermodynamic partitioning equilibrium is assumed in order to calculate the $PEC_{sediment}$ from the PEC_{water}. For the PT 8 products evaluated by DK we have used the approach from the Guidance on the BPR (Volume IV, Part B), which has been accepted by other member states. The equilibrium partitioning method is also widely used during the active substance assessment, to calculate a $PNEC_{sed}$, which is why we at the DK CA prefer this method for calculating the $PEC_{sediment}$ as well. Therefore, we think that this approach should be added to the excel sheets as well. The DK CA finds it necessary to agree on an approach on how to assess the exposure to the sediment compartment from PT8 products. We have seen that different results are derived based on which method is chosen, however we do not have an overview over the degree of difference.		
15.	<u>PT 8 – dipping immersion processes, Qai conversion factor (from $kg.m^{-2}$ to $kg.m^{-3}$)</u>	**Point closed.** The WG agreed to use a	

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19		Meeting date: 12-14 September 2017	
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
	ESD Spreadsheets preparation (SECR) In the spreadsheet PT 8 – dipping immersion processes, the Quantity of a substance applied per m^3 of wood (Q_{ai}, $kg.m^{-3}$) is a set value, usually provided in $kg.m^{-2}$. The conversion factor is still under discussion (if 38 or 40). Therefore, as a quick fix we have included a note advising the user to multiply the application rate in $kg.m^{-2}$ by a factor of 40 (worst case). *For information only.*	default value of 40. The item will be removed from the open issues for the AHEE (item 8.1)	
16.	<u>PT10 – Spraying application – dimensions of the receiving soil compartment</u> ESD Spreadsheets preparation (SECR) The distance travelled by drift, considering a total height of release of 4.25 m (i.e. height of the façade 2.5 m + height of the roof 1.75 m), is calculated in the ESD p.21; its value is 6.9 m. It is then designated as "width of the receiving compartment". In the ESD Fig.5, the value 6.9 m is depicted next to the width of the adjacent soil of 10 cm, resulting in a total width of the receiving compartment of 7 m (6.9 m + 0,1 m); this is not in line with the maximum distance travelled by drift, which was calculated to be 6.9 m. **To be discussed:** The value 6.9 m is the distance travelled by drift, i.e. is the maximum distance, which can be reached by spray. Therefore, we consider that the actual total width of the receiving soil compartment should be maximum 6.9 m. Consequently, if the width of the adjacent soil is 50 cm, the width of the distant soil should be 6.9-0.5 = 6.4 m. Do the WG members agree with this proposal?	**Point closed.** The WG agreed to the proposed correction. Note that the scenario will however be replaced by the scenario for in situ spraying outdoors for PT 8 (see item 2 above).	
	Background		

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19		Meeting date: 12-14 September 2017	
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
	The receiving soil compartment adjacent to the treated house is now considered to be 50 cm distant (instead of 10 cm) according to a decision of the 23rd CA meeting.		
17.	<u>PT10 – Spraying application – ESD Table 10</u> ESD Spreadsheets preparation (SECR) Table 10, covering the emission scenario for calculating the releases from a façade treated by sprayer, indicates that Vsoil(d) is 54.1 m^3, considering that the façade and the roof are treated the same day; also notes that if only the façade is treated, the soil volume distant to treated façade is 27.3 m^3. **To be discussed:** Considering that Table 10 concerns specifically the treatment of a façade, Vsoil(d) should be the volume corresponding to a height of release of 2.5 m (height of the façade). The actual volume value needs to be calculated according to the decision taken in the previous item. Do the WG members agree with this proposal?	Please refer to the previous item (correction was in principle agreed, however no longer relevant due to use of the equations from the ESD for PT 8).	
18.	<u>PT 13 – Fraction of mwf concentrate in diluted mwf fluid (Fconc)</u> ESD Spreadsheets preparation (CH, NL, UK, RCOM PT 8 & 13 #72) Several MS raised the question on which value to use as Fconc. The ESD for PT 13 provides a table of defaults Fconc, per activity and per type of mwf (Table 1, p.15), while a default value of 0.2 is specified in the TAB (ENV 74, v1.3). On the other hand NL considers that the worst-case Fconc depend on the Kow (see "**Background**" for detailed comment). **To be discussed:** Should the TAB entry (ENV 74, v1.3) be revised? We would agree with NL that the recommended worst-case value should depend on the substance (hydrophobic / hydrophilic). What are the views of the WG members?	**Point closed.** The WG agreed that the TAB entry should be revised and the worst case Fconc should be taken into account (depending on the Kow). Note: Only relevant if the biocide is applied via a concentrate and not if used as a ready to use product.	

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19			Meeting date: 12-14 September 2017
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
	Background NL: The fraction of MWF concentrate in the diluted fluid is not a property of the biocide, but depends on the instructions given by the manufacturer of the fluid depending on its composition and purpose. Therefore, this parameter should be a default (D) instead of a variable (S/P). In case of addition to the diluted fluid, 0.05 should be applied as the worst-case. This is the lowest value in the ESD (0.05-0.2) which results in the highest emission to the sewer, as the total mass of biocide that is removed along with the oil phase is minimal. However, no defaults can be given for biocides that are dosed via concentrates, as the worst-case now depends on the biocide's hydrophobicity and could be every value between 0.05 and 0.2. For hydrophilic substances, 0.2 is worst-case as this results on the maximum mass of biocide in the system. For hydrophobic biocides, however, 0.05 is worst-case. Although the total mass is lower than 0.2, the volume of the oil phase is lower as well resulting in less removal during splitting. But, for instance, Fconc=0.1 seems worst-case for Kow=100. Although manufacturers should add biocides to concentrates in a way that the concentration after diluting is efficacious, i.e. the stronger the dilution of the concentrate the higher the concentrations in the concentrate, we suggest to remove dosing via concentrates or add an additional tool that calculates the worst-case Fconc depending on the Kow.		
19.	<u>PT 13 - Working or cutting fluid preservatives – VP reference temperature</u> ESD Spreadsheets preparation (DE, RCOM PT 8 & 13 #58) DE noted that the ESD does not provide a reference temperature for the vapour pressure of the substance. However, DE points out that the Guidance on BPR Vol. IV Part B v.2.0 indicates 20° C as reference temperature for vapour pressure. SECR notes that in the spreadsheet, which implements the ESD, 25° C, will be indicated as reference temperature for vapour pressure (input parameter). Reference is made to footnote 15 in the ESD (vapour pressure of AS and water need to be in line). ***For information only.***	*For information only.*	
20.	<u>PT 13 - Working or cutting fluid preservatives – Calculation of</u>	**Point closed.**	

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19		Meeting date: 12-14 September 2017	
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
	<u>degradation of biocide since last dosing</u> ESD Spreadsheets preparation (DE, RCOM PT 8 & 13 #61) On the calculation of "degradation of biocide since last dosing", DE considers that a realistic time span between last dosing and the start of waste treatment ("t") can only be given for waste management companies. Therefore, DE considers that the calculation of $F_{elim,storage+more}$ apply only for waste management companies and that this refinement should not be used for end-users/on-site treatment. **To be discussed:** What should be the default worst case for t? Should the calculation of $F_{elim,storage+more}$ apply to end users with on-site treatment?	The WG agreed that it should be a set value and no default value should be defined. As a guidance, the the WG referred to the questionnaire in the ESD where a value of 7 days was provided for the shortest storage period in case of disposing off the MWF to an external WWTP.	
21.	<u>PT 13 - Working or cutting fluid preservatives – storage of fluids – DT50/kdeg</u> ESD Spreadsheets preparation (DE, NL, RCOM PT 8 & 13 #69, #70) kdeg (or DT50) is a parameter needed for the calculation of $F_{elim,storage+more.}$ DE asked for clarification on which study the DT50/kdeg originates. NL also pointed out that in metalworking fluids no biodegradation or a long lag-phase is expected, due to low densities of microorganisms (as these are strongly reduced by the addition of the biocide). NL considers that degradation rate constants derived from a screening or water test cannot be applied. According to NL, the degradation rate constant should be experimentally derived (degradation test in mfw) or the hydrolysis rate constant should be applied instead. **To be discussed:** Which study should be the source of DT50/Kdeg?	**Point closed.** The WG agreed to the proposed tiered approach by NL: Tier 1: Use the DT50 from the hydrolysis study. Tier 2: Use the DT50 from a degradation test in MWF.	

Discussion table – Open items related to the emission estimation for PT 8, PT 10, PT 13 and PT 19		Meeting date: 12-14 September 2017	
a) No.	**b) Issue and background Ref. in RCOM**	**c) Open/closed point Conclusions**	**d) Action points Deadlines**
22.	PT 19 – Treated area of skin Dedicated Newsgroup until 10 March 2017 – PT 19, Item 1 and Item 2 (UK) UK considers that fixed skin areas for animals is not appropriate in all cases, especially where the product is intended for small scale use as a lotion / cream to prevent further bites at or near existing ones. UK notes that it is possible that label claims and efficacy data support application to small areas around wounds etc., so the overall area treated is 200cm^2 and not 58300cm^2. UK therefore proposes the ability to reduce areas in those circumstances to realistic levels, when it is clear that not the whole animal is treated (further argumentation of UK is provided in the Background section). **To be discussed:** Do WG members agree with the use of skin areas smaller as the ones included in Table 3.9 of the ESD, when it is clear that application to the whole animal will not take place?	**Point closed.** The WG agreed to the proposal of UK in the case of small scale applications (i.e. to use a value of 200 cm^2). These small scale application should be however reflrected in the way of application (e.g spot treatment with a cream or hand held spray equipment) as well as in the package size.	
	Background: UK notes that if the label claims and efficacy data support application to smaller areas, "such a product would never be applied to the entire horse as it would take a considerable time to apply, would be very expensive to apply (taking multiple packs every day) and horses would not co-operate whilst such a lengthy treatment was undertaken." UK notes, "the reason given for such an approach is that 20% of horse owners in an EU (or DE) survey would treat the entire animal even if labelling told them not to. Under current national legislation, UK would consider this as misuse and an offence by the user but would not use it as grounds for inclusion in an ERA. Efficacy data will prescribe how the product can be used to provide effective control of flies (by repelling them) and that information is detailed on the label. UK considers that any ERA should then follow that use pattern and recommended treatment regime."		

APCP WG Appendices

Appendix 1:

Agenda item 7.2: Naming of active substances

Working Group – Analytical methods and Physico-Chemical Properties (APCP) to the Biocidal Products Committee	
Final minutes – Naming of active substances	
Date of meeting: 05/06 September 2017 Date of draft minutes: 29 September 2017 Date of update: 03 November 2017 Date of final minutes: 14 November 2017	Agenda point: **7.2**
Drafted by: ECHA	**Non-confidential**

Final minutes– Naming of active substances			Meeting date: 05/06 September 2017
a) No.	**b) Main points for discussion**	**c) Summary of comments (comments received from DE, FR, IT, UK)**	**e) Discussion and Conclusions**
23.	**Naming of UVCB substances** **To be discussed:** The document provided for commenting suggested that for active substances, which are UVCB substances, the Guidance for	All commenting member states agreed that the REACH guidance should apply for UVCB substances.	The working group members agreed that the REACH guidance for identification and naming of substance should also be used for biocidal active substance for the naming of UVCB substances.

a) No.	b) Main points for discussion	c) Summary of comments (comments received from DE, FR, IT, UK)	e) Discussion and Conclusions
	identification and naming of substances under REACH and CLP should be followed. Do the working group members agree with this approach?		Therefore, the no differentiation between impurities and main-constituents is made; hence, all constituents contribute to the active substance. It was agreed that concentration ranges of all constituents should be provided in the reference specification, hence the purity of the UVCB substance is by definition 100% and the content of the individual constituents is indicated as a concentration range and not as maximum or minimum concentration level.
24.	**<u>Naming of mono-constituent substances</u>** **To be discussed:** The document provided for commenting suggested that for mono-constituent substances, the efficacy of the constituents should be taken into account for the naming, so that the identity is based on the active constituent, even in a hypothetical scenario where another non-active constituent is present at >80%. **Pros**: • Avoids the risk of a substance being named according to a constituent that does not contribute to the efficacy (i.e. an impurity). • Avoids the situation where the	One member state agreed that efficacy should be the main criteria for identity and naming. Several member states were of the opinion that generally, the REACH guidance should be applied, as the number of problematic cases such as described in the document are likely to be low for mono-constituent substances. It was noted that the REACH guidance already allows some flexibility for taking into account the "technical effect" of the substance. Naming based on efficacy rather than composition could be allowed on case-by-case basis, following discussions in the working group. One member state expressed that the substance definition only takes into account manufacturing method and composition, and therefore properties are principally not identity criteria.	The working group members considered that information about the efficacy of the individual constituents would be needed if the naming should be based on efficacious constituents only. However, this information might be not always available or difficult to generate. Nevertheless, in order to comply with Article 10(1f) of the BPR, the dossier should include information on portion of impurities and non-efficacious isomers. Current approach taken for efficacy considers the substance as such and does not differentiate between the efficacy of the individual constituents. The working group agreed that as a general principle, the REACH guidance for identification and naming should be applied for mono-constituent substances. However, there may be cases where it is relevant to

a) No.	b) Main points for discussion	c) Summary of comments (comments received from DE, FR, IT, UK)	e) Discussion and Conclusions
	substance identity is changed due to an improved purification procedure. **Cons**: • As this approach does not strictly follow the REACH guidance, alignment between different legislations (REACH, CLP) may be lost, which can create confusion. Would the working group members agree to name mono-constituent substances based on efficacy rather than strictly following the REACH guidance? On the other hand, if the REACH guidance is principally followed but exceptions are allowed on case-by-case basis, how should consistency by assured?		consider minor constituents (<10%) for the naming, when these constituents contribute significantly to the activity of the substance. In such cases, the eCA should consult the working group members case by case to decide on the most appropriate name. These questions should be discussed at an early working group meeting (this applies for all points 1-5).
3.	**Naming of multi-constituent substances** **To be discussed:** Similarly, it was suggested that for multi-constituent substances, the efficacy of the constituents should be taken into account for the naming, so that the identity is based on all active constituents, even in a scenario where efficacious constituents are	One member state agreed that efficacy should be the main criteria for identity and naming. Several member states were of the opinion that generally, the REACH guidance should be applied. However, it was noted that the guidance already allows some flexibility for taking into account the "technical effect" of the substance. Naming based on efficacy rather than composition could be allowed on case-by-case basis, following discussions in the working group. One member	The working group agreed that as a general principle, the REACH guidance identification and naming of substances should be applied also for multi-constituent substances. However, in cases where constituents with a content of <10% contribute to the activity of the substance, these constituents may be considered for the naming of the substance. In such cases, the eCA should consult the working group members case by case to

a) No.	b) Main points for discussion	c) Summary of comments (comments received from DE, FR, IT, UK)	e) Discussion and Conclusions
	present at <10%. **Pros**: • Avoids the risk that the substance name includes a constituent that does not contribute to the efficacy or that efficacious constituents are not included in the name. • Avoids the situation where the substance identity is changed due to improved purification procedure. **Cons**: • As this approach does not strictly follow the REACH guidance, alignment between different legislations (REACH, CLP) may be lost, which can create confusion. Difficulty in finding an appropriate cut-off limit for efficacious constituents (i.e. how far below 10% is acceptable?). Would the working group members agree to name multi-constituent substances based on efficacy rather than strictly following the REACH guidance? On the other hand, if the REACH guidance is principally followed, but exceptions are allowed on case-by-case basis, how should	state expressed that the substance definition only takes into account manufacturing method and composition, and therefore properties are principally not identity criteria. With regard to cases (e.g. insecticides with stereo-centres) where some efficacious isomers are present at <10%, all member states agreed that such isomers should be considered for the naming. There was no general agreement for how low concentrations of the efficacious isomers would be acceptable.	decide on the most appropriate name. Consistency with other legislations (REACH, CLH, and PPP) should be taken into account for the naming of active substances.

a) No.	b) Main points for discussion	c) Summary of comments (comments received from DE, FR, IT, UK)	e) Discussion and Conclusions
	consistency by assured?		
4.	**<u>Naming of substances where efficacy of the constituents is not known</u>** **To be discussed:** For mono- and multi-constituent substance, the document provided for commenting suggested that in case it is not known which of the individual constituents contribute to the efficacy of the substance, the REACH guidance should be strictly applied. Do the working group members agree with this approach? For active substances where it is not known which constituents contribute to the efficacy, should applicants be requested to generate such data?	One member state was not in favor of requesting data on efficacy, while another member state expressed that it should be considered to request always efficacy data for the individual constituents (or isomers) for multi-constituent substances (including substances with stereoisomerism).	The working group discussed the possibility of requesting efficacy data for all individual constituents during the approval process, but it was noted that this is not the current approach applied for deciding on the efficacy of an active substance. However, due to Article 10 (1f) of the BPR there is a legal requirement for the applicant to provide information on portion of non-efficacious isomers and impurities. When this information is not in the dossier, the eCAs may consider requesting clarification from the applicant if such information is available to them. If it is confirmed that only certain isomers are efficacious, the working group will decide case by case which constituents contribute to the naming of the substance.
5.	**<u>Naming of substances with ISO names</u>** **To be discussed:** The example of substances for which an established ISO name exists was raised by several member states during commenting. Do the working group members agree that when the composition of the substance is in agreement with an available ISO name, that the ISO name should be used, even	Several member states expressed the opinion that when a suitable ISO name is available, this name should be used in order to achieve consistency with other regulations.	ISO names of active substances are internationally recognised and used; therefore changing an ISO name may confuse the customers of the applicant. Hence, a modification of an ISO name should proposed carefully with consultation of applicant. Generally, the working group members agreed to keep existing ISO names. However, in exceptional cases a change of an ISO name might not be avoidable. In this context, the working group members agreed that an ISO

a) No.	b) Main points for discussion	c) Summary of comments (comments received from DE, FR, IT, UK)	e) Discussion and Conclusions
	when this results in a deviation from the REACH guidance?		name could only be used if the ISO definition of the substance is met.

Appendix 2:

Agenda item 7.3 – Tolerance limits

Working Group – Analytical methods and Physico-Chemical Properties (APCP) to the Biocidal Products Committee	
Final minutes – Tolerance limits of active substances in biocidal products	
Date of meeting: 05/06 September 2017 Date of draft minutes: 29 September 2017 Date of final minutes: 14 November 2017	Agenda point: **7.3**
Drafted by: ECHA	**Non-confidential**
eCA: United Kingdom	

Final minutes – Tolerance limits of active substances in biocidal products			Meeting date: 05/06 September 2017
a) No.	**b) Question raised at e-consultation and question to the working group members**	**c) Summary of replies (comments received from DE, EE, NL, DK, EL, IT)**	**e) Discussion and Conclusions**
25.	Are tolerance limits for active substances in products are required to be submitted by	The tolerance limits indicated in the Guidance on the BPR: Volume I. Part A; Chapter III:	The working group members agreed that there is no need to indicate explicitly tolerance limits

Final minutes – Tolerance limits of active substances in biocidal products			Meeting date: 05/06 September 2017
a) No.	**b) Question raised at e-consultation and question to the working group members**	**c) Summary of replies (comments received from DE, EE, NL, DK, EL, IT)**	**e) Discussion and Conclusions**
	applicants? The Guidance on the BPR: Volume I. Part A; Chapter III: Requirements for Biocidal Products indicates tolerance limits, however it has been noted that member states have not been including them in their PARs. Therefore, is it the case that 1. other member states assume the applicant is adhering to the active substance tolerance limits at manufacture and not requesting them OR 2. other member states are requesting tolerance limits, but not including them in the PAR The working group members are invited to discuss the need to supply tolerance limits for active substances.	Requirements for Biocidal Products originate from the Manual on development and use of FAO and WHO specifications for pesticides. It was agreed to apply these limits at the workshop on storage stability and physical-chemical properties in March 2013. However, deviations from the limits are possible if justified. Therefore, only in cases where the applicants deviating from these values, tolerance limits should be indicated. In addition, the tolerances indicated in the FAO/WHO document are not fully applicable to the concept of product family as the indicated concentrations are differ from one BP to another, hence multiple tolerances would apply within one BP family. The tolerances shall be applicable for both the single BP and the BP family with the consequences that the agreed approach may require amendment. It should be decided by the human health and environment working group members whether the tolerance limits have to be considered for the risk assessment of the BP and whether these values are needed for the PAR. The verification of the tolerance limits may be in the remit of the national enforcement office.	in the Product Assessment Report (PAR) if applicants follow the Guidance on the Biocidal Products Regulation. In cases where the tolerance limits provided by the applicant are not in accordance with the guidance, then the differences should be stated in the PAR.

List of Attendees (Annex I)

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