WG-V-2016

Final minutes

7 April 2017

Minutes of WG-V-2016

22 – 25 November 2016

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-V-2016 (22 November 2016)

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 presentations 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.

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

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

5. Agreement of the draft minutes from WG IV 2016

Comments on the draft minutes were received as follows:

General agenda items: FI, FR

ECHOC: applicant

The comments were taken into account and the updated draft minutes were agreed by the working group members.

6. Follow up of previous working group meetings

6.1 Follow-up of previous working groups

The chair explained that all open issues of previous working group meetings have been compiled (with deadlines when possible). As it seems that ECHA and the CA have not

(always) been informed whether the requested data have been submitted to the eCA, ECHA will follow up with the eCA to see whether the requested data has been received.

The chair referred to the last WG meeting and informed that a new reference specification has been set for Fludioxonil. An e-consultation was launched and the eCA (DK) replied to the issues raised.

6.2 Technical Agreements for Biocides (TAB)

The chair explained that the TAB was compiled by the decisions made at the previous WG meetings and TM, the document was for commented via e-consultation. The WG members went through the document comment by comment and agreed on the final version.

7. Discussion on the active substances

7.1 L-(+)- Lactic acid PT02, 03, 04

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

7.2 Copper PT02, 05, 11

All open issues were discussed by the working group members. The reference specification and reference source have not been agreed and will be followed up by an e-consultation including the Human Health and Environment working group members.

8. Technical and scientific issues

8.1 Data requirements for precursors of in situ generated active substances

The issues raised during the e-consultation was discussed by the working group members. ECHA will prepare an updated version of the document based on the discussion.

Minutes of Human Health WG

WG-V-2016 (22-23 November 2016)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 22 participants present, of which seven 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. Seven members followed the discussions remotely.

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

2. Administrative issues

SECR gave a brief presentation on housekeeping and administrative issues.

SECR welcomed the new members and informed that a welcome package is available for new nominees. The deadline for nominating the members for the ad hoc Working Group on Microorganisms is extended until 25 November 2016.

SECR informed the participants that in 2017 the WG meetings will be spread over two weeks and there will be a change in the order of some WGs. The new dates are available on ECHA website and the confirmed dates of WG-I-2017 will be published on S-CIRCABC by 2 December 2016.

SECR invited the stakeholders and eCAs to remind the applicants that the case owner contact data on R4BP 3 should be up to date and according to the Code of Conduct for Applicants, they should register with the SECR at least 14 days before the WG meeting, if they wish to attend the discussions on their substance.

3. Agreement of the agenda

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

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

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

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

The minutes were agreed without further changes.

6. Discussion of active substances

6.1 Diamine (eCA PT) PT 8

The WG agreed that systemic risk assessment is required together with the local risk characterisation. Two ad hoc follow-ups will close the points on 1) the NOAEL for systemic toxicity in the combined chronic-carcinogenicity study and reference values setting, and 2) dermal absorption.

6.2 (L)+ Lactic acid (eCA DE) PT 2, 3, 4

There were no open points for discussion and therefore no discussion took place. The WG agreed with the assessment performed.

6.3 Copper (eCA FR) PT 2, 5, 11

The WG agreed on the remaining open points related to reference values and exposure assessment. All points were closed.

7. Technical and guidance related issues

7.1 Update on guidance development

The CA consultation for *Vol V Disinfection by-products* was concluded on 9 November, and the publication is expected to take place in December 2016.

SECR informed of the joint guidance development by ECHA and EFSA on endocrine disruptors. This joint guidance should not include any specifics for either biocides or pesticides; the regulatory consequences should not be included, as these will differ for biocides and pesticides.

The revision of the guidance on technical equivalence will be started in 2017.

SECR will provide the next version of TAB during the first quarter of 2017. Members were requested to send any proposals for TAB entries to SECR in the functional mailbox biocides-bpc-active-substance@echa.europa.eu.

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

SECR informed that eleven recommendations have been agreed so far by the Working group and they are all publicly available on the ECHA website.

SECR gave an update on the activities of the HEAdhoc:

- The update of Recommendation no 6 "Methods and models to assess exposure to biocidal products in different product types - Version 2" is ongoing;
- The revision of the HEEG opinion 15 – "On the paper by Links et al. 2007 on occupational exposure during application and removal of antifouling paints" will possibly start during the course of 2017;
- A recommendation will be developed based on the British Coatings Federation PT 21 survey, timeline to be defined;
- The update of the HEAdhoc Recommendation no. 9 "Hand disinfection in hospitals by professionals – Inhalation and dermal exposure during hand disinfection" is foreseen to be presented at the WG-I-2017;
- The recommendation on the spray study in slaughterhouse for high-pressure disinfection is foreseen to be presented during the course of 2017.

7.2(a) Recommendation "Teat disinfection products for veterinary hygiene (PT 3)"

Comments on the ConsExpo models used in the recommendations were received from RIVM. The input will be forwarded to the HEAdhoc members for further consultation. The recommendation is scheduled for agreement at the WG-I-2017.

7.2(b) Recommendation "New defaults indoor Transfer Coefficient"

SECR presented the meeting document WGV2016_TOX_7-2b, including the new values to be used for indoor Transfer Coefficient. These values refer to the revision of the US-EPA SOP for residential exposure in 2012 and include a value for children exposure.

Comments were received by ASOs in order to correct the data of transfer coefficient agreed by US EPA included in Table 1. The modifications did not affect the conclusions of the recommendation and were included into the document during the meeting.

The Recommendation was agreed by the WG meeting. SECR will proceed to finalise the document and publish it on the HEAdhoc website.

7.3 Update on Ad hoc Working Group- Assessment of residue transfer to food

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

7.4 Need to perform systemic and local risk characterisation

The WG discussed the need to perform systemic risk characterisation (RC) in various situations. The considerations below reflect this initial discussion where the intention was not to reach an agreement. Further elaboration of any of the approaches will be necessary. Therefore, the below considerations should not be taken as agreements but only as an account of the discussion.

Local RC is qualitative or semi-quantitative and much less developed than the systemic RC. Several members questioned the use of RMMs as an argument for not performing systemic RC; although no risk would be expected in systemic RC, this should nevertheless be assessed.

The members considered that systemic RC might not be needed if there are no clear systemic effects at the limit dose. However, if the data package does not cover all endpoints due to significant waiving, the systemic RC could still be needed. If there is significant waiving and no systemic effects, the missing information could be an argument to perform the systemic RC with the available information to cover the uncertainty. If the concentrations tested were lower than the limit dose, e.g. because of local effects, then a systemic RC might usually be required.

If there are both systemic and local effects, it is very difficult to conclude that local effects are much more critical than systemic effects because local effects are concentration dependent while systemic effects are dose dependent. Extreme sensitizers might be an exception, possibly not requiring systemic RC, but also this was questioned.

It is also difficult to conclude that systemic effects are secondary to local toxicity as there should be a degree of certainty to conclude. If there is uncertainty, it was argued that the effects should be considered as systemic.

Specific measures might be needed for substances that have low oral absorption, because such substances would always have very low AEL values.

Systemic RC might not be necessary if the substance is endogenous and/or included in the diet.

AEL derivation and selecting NOAEL

Normally AEL values would be derived for the purpose of performing systemic RC, and systemic RC would always be performed if it is possible to derive AEL values. One member however suggested that systemic reference values could always be derived even if a systemic RC is not performed, similarly to deriving ADI and ARfD. Another member suggested that the MOE approach could be an alternative to reference values.

If limit dose was not tested, the lowest top dose NOAEL should be used as a reasonable starting point for AEL derivation. The selection should however be flexible, also noting recent examples where the lowest top dose was considered unnecessarily conservative.

Selecting AF

If no systemic effects were seen, some members considered it acceptable to adjust the AF. Others however commented that the AF should remain as 100 because there is no knowledge of the possible effects and their nature.

It is necessary to consider whether systemic effects that are not adverse could become adverse at higher doses. It was therefore argued that the AF should not be lowered if there are systemic non-adverse effects, but adjusting could be considered if there are no systemic effects at all.

Uncertainty analysis

SECR proposed that in the context of the uncertainties discussed, as well as any other uncertainties, it would be useful to include an uncertainty analysis in all CARs. Such an analysis would indicate the sources of uncertainty and specify whether they would be expected to overestimate or underestimate the risks.

In addition to any approach selected, the use of an uncertainty analysis should be further investigated and could be included in the Assessment Reports.

7.5 ADI and ARfD derivation for biocidal active substances

SECR presented the meeting document, which was a revised proposal amended according to the comments received from the WG members and from the Pesticides Unit in EFSA. SECR considered it appropriate to provide the draft document to the EFSA colleagues, as the ECHA BPR guidance indicates that the principles for ADI and ARfD setting in plant protection products should be followed.

The WG agreed to derive always ADI and, if necessary, ARfD if appropriate information is available, unless it is not scientifically justified and to report them in the assessment report of each PT for which the active substance is under evaluation. In case these values are not used in the risk assessment, a standard phrase could be included where relevant: "*The value was not used in the current assessment as no consumer exposure via food is expected in the PT/uses assessed"*.

The document was agreed by the WG meeting with some minor changes. SECR will finalise and publish the document.

7.6 Data requirements for precursors of in situ generated active substances

SECR introduced the document proposing an approach for the information to be required for precursors of in situ generated active substances. Briefly, the following was proposed:

1. The applicants should provide all information available to them;
2. The data requirements of BPR Annex III would apply (with flexibility and taking note of BPR Annex IV);
3. The guidance on substances of concern (SoC) (ECHA Guidance Vol III Part B, Annex A) would apply if the precursor is to be considered as a substance of concern;
4. Further information could be requested for SoCs;
5. According to the SoC guidance above, fully quantitative risk assessment should be performed for precursors that fall in Bands C and D of the banding scheme, as well as for precursors that are biocidal active substances.

Several members considered that BPR Annex III was intended for formulations including an active substance and would not fit well for precursors. It was considered that these data

requirements could apply if there were information on an active substance included in the formulation, allowing a quantitative risk characterisation to be performed. This would not be the case for precursors.

Some members were also of the opinion that the Guidance on substances of concern would not apply for substances that are not co-formulants. SECR considered that although the Guidance refers to co-formulants, this would not impede using it for precursors if considered relevant.

Members also noted that if no information were to be requested in addition to BPR Annex III, then it would not be possible to perform a risk assessment for the precursors. There was a discussion but no conclusion on whether a quantitative risk characterisation would always be necessary for the precursors.

The WG did not agree on the proposal. SECR will inform the members of the steps to follow.

Post-WG note: an e-consultation has been launched with the deadline of 13 January 2017:

- Path: /CircaBC/echa/BPC-WG/Newsgroups/TOX WG - Precursors of in situ generated active substances - follow-up WG-V-2016
- https://webgate.ec.europa.eu/echa-scircabc/w/browse/01d99033-1761-4e2b-8f3a-e845caedc5dc

7.7 Information on batches used in toxicity testing

SECR introduced the proposal on the information to be provided on the batches used in toxicity testing. The members welcomed the proposal and considered it useful. Several members expressed their preference for one or the other sample table in the document (tables 2a and 2b). It was agreed that the format can remain flexible and the eCA can choose which version to use based on the available data.

It was suggested by one of the members to include an additional column/row on whether the batches can be considered representative, i.e. support the proposed technical specification. This proposal was supported and will be implemented.

An ASO representative indicated that their members were still in the process of commenting on the document and the comments will be sent later.

7.8 Dermal absorption of antifouling products

The WG discussed the SECR proposals in the context of the meeting document. The WG agreed on the document following detailed discussions on wording; please see the document that will shortly be published on the ECHA website[1].

7.9 Dermal absorption of anticoagulant rodenticides

SECR presented the meeting document. The proposal to set a refined default value of 4% for grain bait formulations containing second-generation anticoagulant rodenticides was agreed by the WG members. During the discussion, questions were raised regarding the legality of using studies submitted by applicants at active substance approval or applications for product authorisation to derive default factors that could then be used for all applicants at the renewal of product authorisations. SECR will clarify this before proceeding.

The members supported the FR proposal to collect the available information on dermal absorption of first and second-generation anticoagulant rodenticides. A member informed that they had re-evaluated the dermal absorption studies submitted for active substance

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

approval based on the current guidance and that this information could be taken into account. SECR will liaise with FR in order to determine the details and requirements of information. SECR will provide further details on the collection of dermal absorption studies to the MSCAs after the meeting.

The second proposal of extrapolating data or default values between formulation types in a qualitative way had not been supported by WG members during the written consultation. A member indicated that the differences in dermal absorption between solid formulations are in general low. Another member indicated that due to the urgency the proposal could be reconsidered. Overall, the WG members considered that the assumptions for establishing extrapolations between different formulations included in the proposal were not sufficiently justified and that read-across between different bait formulations should be restricted to very few cases.

7.10 Risk assessment of preservatives (PTs 6-13)

SECR presented the thought starter that was provided as a meeting document. Three main issues were identified as problematic in the risk assessment of articles treated with preservatives: dermal absorption, exposure estimation and refinement options. The WG acknowledged the issues but also considered difficult to provide input on a general level. It was proposed to identify specific problems and address them case by case. CEFIC informed that within their organisation there are working groups, dedicated to some preservatives (PT 6, 7, 11 and 12), dealing with technical issues.

SECR invited the MSCAs and stakeholder organisations to provide information or case studies to better define the problems and to support the WG in defining ways forward.

7.11 Discussions on reference values and absorption values

SECR introduced the meeting document explaining that the intention of this proposal was to support the discussions on reference values. SECR proposed the eCAs to provide chapters 14.1 and 14.2 of the new CAR/CLH template to support the WG discussions and clearly present the proposal for reference values. SECR acknowledged that this would constitute an additional task for the eCAs when the old CAR template has been used, but such a structured approach could help the discussions and avoid ad hoc follow-ups. It was suggested that only concise information on the critical findings at the LOAEL should be included in the tables, as these chapters should provide a quick overview of the different studies and NOAELs, which could be used for reference value derivations. A more detailed evaluation of the studies would be presented in the context of effects assessment in chapter 3 of the CAR/CLH template or in Doc IIA of the old CAR template.

The members welcomed the proposal as this will help understanding the reference value derivation and facilitate discussions and decision-making. It was suggested to include the local reference values (e.g. NOAECs and AECs), as well as the dose levels used in the studies. SECR clarified that the tables in section 14.1.1 refer to acute, medium-term and long-term effects seen in the studies. These changes will be implemented in the updated CAR/CLH template.

Questions were raised regarding the implementation timelines and at which stage this information should be provided in the process flow. The SECR clarified that for CARs in the new format, this information will already be available since these chapters are included in the new CAR/CLH template. For CARs in the old format, SECR proposed this information to be provided together with the CAR, or at the latest with the updated RCOM. The intention would be for the eCA to update the information to reflect e.g. any agreements made in the RCOM. SECR proposed to apply this new approach from process flow 17, where the updated RCOM would be provided by 13 February 2017. SECR also encouraged the eCAs to provide this document for the WG I meeting in January 2017 if possible, as this would facilitate the discussions.

This proposal was supported by the WG members and will be implemented.

8. Any other business

8.1 Other information & lessons learned

SECR informed that the checklists for accordance check will soon be available for all WGs. They will then be merged and provided to the MSCAs. The eCAs would be expected to use this checklist and provide it together with a CAR when submitting to ECHA. SECR welcomed any input on the Human Health part of the checklist anytime.

The combined CAR and CLH template will be provided for the final commenting period by BPC, RAC and CARACAL. Publication is expected in February 2017.

SECR informed that the ad hoc follow-up procedures are currently being harmonised between the WGs and the members will be informed as soon as a common procedure is available.

Minutes of Efficacy WG

WG-V-2016 (24 November 2016)

1. Welcome and apologies

The Chair welcomed all participants to the 14th Efficacy WG meeting. There were four core and three alternate members who participated in the meeting. In addition, seven flexible members, one rapporteur and three ASO representatives (only for the non-confidential agenda items) of 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

ECHA gave a brief summary on the administrative issues.

3. Agreement of the agenda

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

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

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

5. Agreement of the draft minutes from WG-IV-2016 and updated draft minutes from WG-III-2016

The Chair informed that comments for the minutes of WG-IV-2016 had been received from FR and EL. The comments, which were mainly editorial, were accepted by the EFF WG. For minutes of WG-III-2016 the paragraph regarding point 7.2 "Efficacy testing of treated articles – (health) claim matrix" had been further clarified by ECHA, and these minutes were also agreed by the EFF WG.

6. Discussion of active substances[2]

6.1 (L)+Lactic acid (eCA DE)

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

The EFF WG agreed on the evaluation of the eCA.

6.2 Copper (eCA FR)

There was one remaining open point concerning efficacy for discussion. The EFF WG considered necessary to indicate in the CAR the fact that different types of devices generating an active substance by electrolysis might have an influence on efficacy at product authorisation stage. The phrase *'If the active copper ions are produced in situ by electrolysis the device can affect the efficacy. Therefore, at product authorisation the efficacy tests should always be done with the electrodes in a specified device or devices with a defined output range. Information on how the device is protected for under- and overdosing should be given.'* will be added to the CAR. In addition, this horizontal

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

conclusion agreed by the EFF WG will be included in the Technical Agreements for Biocides (TAB).

6.3 Status of on-going ad hoc follow-up: silver zinc zeolite (eCA SE)

SE presented new test submitted by the applicant to support efficacy of silver zinc zeolite in PT7 and 9 together with a table containing specific uses in respective PTs, for which efficacy in the opinion of SE is demonstrated. In this new test three different materials were tested under adapted, simulated in use conditions. Additionally comprehensive justifications concerning relevant target organisms were provided. Overall SE finds this study sufficient to prove efficacy of silver zinc zeolite in the above mentioned PTs. The EFF WG considered this study as acceptable, appreciated the effort made by the applicant and agreed with the eCA.

7. Technical and guidance related issues

7.1 Guidance development

ECHA gave an overview of the EFF guidance projects in progress:

- Vol II Assessment + Evaluation(Parts B+C). During PEG consultations ECHA received 294 comments, PEG meeting took place 26 October 2016 with a good progress. Post PEG meeting documents being revised and sent for cross check to PEG members. CA consultation foreseen in December 2016 and publication in January/February 2017.
- Transitional Guidance for PT 14. Some final comments needs to be clarified, publication is foreseen in December 2016.
- Vol II update to Part A. It was sent for revision by the EFF WG members, deadline for comments 20 December 2016, discussion is foreseen in January 2017 at EFF WG meeting.
- Vol II update to PT5. Following ECHA Disinfectants Project the updated draft will be consulted and discussed at PEG meeting in 2017.
- Vol II update to PT11/12, and PT19 are planned to be developed in 2017.

7.1.a. Appendix 4 of the PT1-5 Efficacy Guidance

ECHA and NL presented discrepancies spotted out in Appendix 4 [Overview of (EN) standards, test conditions, and pass criteria] of the Transitional Guidance (TG) on Efficacy Assessment for Product Types 1-5, Disinfectants. The required log reductions for textiles in PT2 and in PT3 are 7/6 and 4/3 for bacteria/yeast, respectively, and a question coming from the industry was whether the higher log reductions in PT2 are correct. The EFF WG concluded that EN 16616 requires log reductions of 7 and 6 for bacteria and yeasts, respectively. The ASTM E2406 and 2274 tests, recommended in the TG for products not intended to be used in washing machines, do not, however, have specified acceptance criteria. Since in PT2 and PT3 both EN 16616 and ASTM tests are mentioned for textiles, it was agreed that required log reductions should be amended to specify the different requirements for different test methods and application types (machine wash and hand-wash processes), and an explanatory footnote should be added. FR and NL will cross-check the ASTM tests for verifying whether required log reductions of 4/3 for bacteria/yeast can be justified, and Cefic will consult CEN/TC216/WG2 for their view on the reasonable log reductions to be required.

Another point was that soiling conditions for textiles in PT3 are missing from the guidance. It was agreed that they should be amended to note 4, but the interfering substance and its dosing (g/l or g/kg) should be consulted with CEN. Cefic will try to get feedback from CEN before WG-I-2017. For the time being the applicants should be recommend to use the soiling with blood according to EN16616. Defining the worst-case textile type was also discussed, and it was brought up that EN16616 specifies the fabric type to be used. Cefic will ask for information on the selection of this fabric type from CEN/TC216/WG1.

It was agreed that ECHA will amend Notes to the reader / 7 on PT5 based on the outcomes from the Disinfectants project.

The other required log reductions were corrected as well to be consistent with the criteria given in the respective test methods: (PT1 hygienic hand wash / yeast / 2,1 test: 4 → 2; PT1 hygienic hand wash / fungal spores / 2,1 test: 4 → 2; PT2 hard surfaces / bacteria / 2,2 test: 4 → 4/5; PT2 hard surfaces / yeast / 2,2 test: 3 → 3/4; PT3 hard surfaces + PT3 hoof disinfection + PT4 hard surfaces / mycobacteria: 5 → 4).

To be in line with the main text of the guidance the EFF WG agreed to add additional footnotes:

- for PT3 teat disinfection on the optional phase 2 step 2 test for yeasts - NL will send a proposal to ECHA,
- for PT 2 and PT4 hard surfaces on the phase 2, step 2 test for viruses. The prEN 16777 will not be added.

For PT4 surfaces in drinking water/veterinary water systems it was agreed that the testing temperature of 20°C should be lowered, possibly to 15°C - DE will check from PT5 experts.

Note 4 on soiling conditions was amended. For PT4 general claims and for beverage industry and breweries dirty conditions (3 g/L bovine albumin) are required. Specific interfering substances will be kept only for milk industry (10 g/L skimmed milk) and meat industry (3 ml/L sheep erythrocytes). For PT5 the addition of *Legionella* will be verified by ECHA.

For Note 9 it was agreed that Cefic will provide examples concerning contact times longer than 5 min.

Some other minor clarifications and corrections were also agreed upon. The corrected version of Appendix 4 of the PT1-5 Efficacy Guidance will be provided for agreement in WG-I-2017.

7.2 Efficacy of in situ generated active substances (ECHA)

ECHA presented the draft manual on evaluation of in situ generated active substances, which had been prepared according to the comments obtained in EFF WG-IV-2016. The EFF WG members agreed on it with some minors corrections. The final document will consist of APCP, HH, ENV and EFF part.

8. AOB

8.1 Testing to prove that co-formulants are not active (NL)

This point was combined with agenda item 8.5 as both covered similar issues. NL informed that some doubts aroused during evaluation of the dossiers submitted as a part of applications for biocidal product authorisations. The biocidal products quite often contain some substances, which are potentially active. It has a significant impact on HH and ENV part of the evaluation, and the way how to determine if the substance is active or not should be determined. NL prepared a proposal for discussion, and in addition presented CEN document CN2016 WGV how to assess the function of potential active ingredient. DK included two examples in the working document, one with the biocidal product containing isopropanol declared as a denaturing substance, and the second with silicon dioxide declared as an anti-caking agent to change the physical form of the product.

The EFF WG agreed that both proposals, i.e. NL and CEN should be considered together as the approach for tier I and II are very similar. In addition to set up cut-off values would be very helpful, however very difficult to determine.

For the time being it was agreed that the EFF WG will focus on CEN approach and in addition consider the cut-off criteria proposed by NL for tier I and tier II. The members were invited to provide some examples from the submitted dossiers giving some indications where tier I and II approaches are possible/impossible. In addition, the establishment of a list specifying different functions of co-formulants, e.g. pH regulator, solvent, acid for

detergent effect in the biocidal products, would be very useful to have common understanding. This should be done in cooperation with the experts form the APCP WG as they can provide relevant information on the different role of co-formulants.

The discussion will be continued by the EFF WG in January and the outcome will be communicated to CEN.

The EFF WG members were invited to send comments on the NL and CEN proposal, especially related to tier III by Friday, 9 December 2016.

8.2 Disinfection of packaging before filling (NL)

NL has received several applications for biocidal products to be used for the disinfection of food/beverage/medicine containers prior to filling ("aseptic packaging"), considered by NL as surface disinfection (PT2, PT4). Due to the high temperatures and short contact times applied, the standard EN tests are not directly applicable. NL was thus asking for advice on:

1) what kind of tests are needed,
2) which target organisms are relevant,
3) how to deal with variations in packaging machines, and
4) is testing with spores of *Geobacillus stearothermophilus* mandatory.

It was brought up that the Hazard Analysis and Critical Control Points (HACCP) procedures cover monitoring the success of aseptic packaging, but efficacy still has to be demonstrated for product authorisation. The EFF WG agreed that semi-field studies should be required, and that efficacy does not need to be demonstrated for each individual packaging machine, if the worst-case conditions for disinfection (e.g. shortest contact time, lowest temperature, lowest relative humidity, lowest dose) are tested.

In these uses, where disinfection is a combined effect of the high temperature and the disinfectant, bacterial spores are probably the most resistant target organisms. The opinion of the EFF WG was that exceptionally, even if only spores have been tested, also bactericidal, yeasticidal and fungicidal claims can be made, but the applicant has to justify that spores are the most resistant target organisms for the claimed use.

The EFF WG agreed to add a note on the requirements agreed for this use for PT4 in the TAB. NL should also verify at CA level whether some specific uses (e.g. medicinal packaging) fall under the scope of the BPR.

8.3 Waivers for groups of products (NL)

NL gave an oral update of the results of the ongoing discussion at CEN TC216 WG5 related to possible waivers for groups of biocidal products, especially grouped in BPF. CEN prepared a cornerstone approach draft document already commented by its members. For the time being there is no solution to avoid efficacy testing for specific groups of products, as the issue is very complex and quite complicated the discussion is ongoing and the EFF WG members will be informed on the progress at later stage.

8.4 Efficacy testing of biocidal products to be used in disinfection of textiles in combination with a detergent (NL)

NL has received questions about efficacy testing of biocidal products to be used for disinfection of textiles. The key questions are:

1) is it always mandatory to test the combination of the disinfectant and detergent,
2) do all different detergent-disinfectant combinations need to be tested,
3) which testing conditions (time, temperature, etc.) should be used, and
4) can specific detergents be mentioned in the SPC.

NL had drafted proposed solutions to the questions and asked for the opinion of the EFF WG. In general the EFF WG agreed that phase 2 step 2 test should be done as a minimum with the disinfectant/detergent combination, and that in principle all disinfectant/detergent

combinations and various conditions should be tested, unless worst-case conditions can be justified. It was also noted that the type of textile and type of detergent have an effect on the disinfectant efficacy. BS EN ISO 6330:2012 includes a reference detergent and ballast, and could be consulted. Cefic brought up that domestic and professional applications differ in the sense that in domestic machines there is only one combined step, whereas professional machines usually have different separated steps for detergents and disinfectants (multistep process). EN 16616 is based on a combined cycle, and apparently there is currently no guidance available for testing a multistep process. Whether detergents can be mentioned in SPC under other information could not be verified by the EFF WG, and should be clarified from CG.

It was concluded that at the present state intensive testing would thus be required, and some simplification and general guidelines would be needed. Due to the complexity of this issue it will be followed up after acquiring further information.

8.5. Denaturing substances (DK)

See agenda item 8.1.

8.6 TAB – proposals for inclusion (ECHA)

ECHA checked all e-consultations launched in 2016 as well as the EFF WG discussions. Based on this ECHA proposed to include into the TAB the following items:

- Insecticide against crawling and flying insects intended to be used in aircrafts,
- Shelf life of bait products in PT18,
- PT14: Applications for major changes with lower concentration of an active substance,
- Devices generating the active substances by electrolysis.

ECHA will prepare proposals adjusting these items to the TAB scheme. They will be presented during next meeting and included into TAB, if agreed.

8.7 Criteria for accordance check - template (ECHA)

ECHA presented a revised draft of accordance check template in line with the last EFF WG discussion in September. The EFF WG agreed with the revised version. It will be compiled with accordance check templates for APCP, HH and ENV.

8.8 Other information and lessons learnt (ECHA)

ECHA informed that updated working procedure for UA applications is published on ECHA website together with timelines for the peer review process in 2017. According to these timelines two additional virtual EFF WG meetings are foreseen (April and June) and they will be confirmed beginning next year. In January under agenda item 6 an early EFF WG discussion will take place on cyphenothrin (PT18).

8.9 PT18 – Deltamethrin based product (EL) - closed session

EL presented a room document concerning an application for national authorisation for a deltamethrin Wettable Powder (WP) formulation intended to be used as a crack and crevice treatment indoors against crawling and flying insects exerting 2 months residual effect, for which the applicant has submitted efficacy studies only with a deltamethrin Suspension Concentrate (SC) formulation at the same dose rate of active substance and application method. EL had serious concerns to extrapolate efficacy between these formulations based on the results of a relevant paper. Hence, EL asked for other working group members' opinion on whether the submitted efficacy studies with the SC formulation are adequate, or if further bridging studies to prove that these products are equivalent in terms of their residual effect are needed.

The EFF WG members agreed with EL proposal that at least bridging efficacy studies are needed. Bridging studies could be laboratory studies testing residual effect of the products

at the same dose of active substance for 2 months on porous surfaces against one cockroach species, preferably a large one (Oriental or American cockroach), and against houseflies or preferably a wasp species, as the worst cases for the general claims against crawling and flying insects, respectively.

UK mentioned that the claimed crack and crevice treatment is an inappropriate treatment against flying insects. In line with this comment, EL clarified that flying insects do not hide into cracks and crevices like crawling insects, and that the treatment against flying insects should be spotted treatment (on surfaces where flying insects rest) and this should be revised in the SPC. In that case UK suggested that field studies with spotted treatment indoors against flying insects (mosquitoes, houseflies, wasps) should be provided. EL agreed that such studies would be useful to substantiate better this application method. However, EL indicated that according to the TNsG for PT 18&19 no field studies for indoor surface treatment against flying insects are required and probably simulated-use studies in chambers with treated walls could support this claim.

Minutes of Environment WG

WG-V-2016 (23-24 November 2016)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 19 participants present, of which six were core members, two alternate members and seven flexible members. In addition two rapporteur and one expert was present in the meeting. Two representatives from accredited stakeholder organisations were present for agenda item 7. Applicants were registered for their specific substance discussions.

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

2. Administrative issues

SECR gave a brief presentation on housekeeping and administrative issues.

SECR welcomed the new members and informed that a welcome package is available for new nominees. The deadline for nominating the members for the ad hoc Working Group on Microorganisms is extended until 25 November 2016.

SECR informed the participants that in 2017 the WG meetings will be spread over two weeks and there will be a change in the order of some WGs. The new dates are available on ECHA website and the confirmed dates of WG-I-2017 will be published on S-CIRCABC by 2 December 2016.

In addition, the SECR invited the stakeholders and eCAs to remind the applicants that the case owner contact data on R4BP 3 should be up to date and according to the Code of Conduct for Applicants, they should register with the SECR at least 14 days before the WG meeting, if they wish to attend the discussions on their substance.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the WG members to provide any additional items. SECR added one additional item under AOB. The Chair further indicated that due to parallel sessions, the items under point 7 and 8 will be handled in a flexible way. The agenda was agreed.

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

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

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

The minutes were agreed without further changes.

6. Discussion of active substances

<u>6.1 (L)+ Lactic acid (eCA DE) – PT 2, 3, 4</u>

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

Action SECR:

- PT 4: Add the proposed values for cleaning frequency for small and large breweries to the **TAB** (Small breweries: Once a week, 43 weeks per year / large breweries: 10 times per day, 300 days per year).
- PT 4: Question if splitting up the release to on-site/off-site STP in the case of large breweries is relevant and the proposed percentage (on-site = 33% / off-site = 67%) to be send to the **AHEE**.

6.2 Copper (eCA FR) - PT 2, 5 11

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

Action SECR to add the following conclusions to the **TAB:**

- PT 2: Public swimming pools with the default size provided in the ESD are emptied over three days to the sewer system. In the light of further experience, this default value may be adapted in the future
- PT 5: Total water consumption per occupied hospital bed: Based on information provided by WG members during the meeting on the water consumption per bed in hospitals on national level, a default value of 0.7 m^3/d was agreed
- PT 11: If large open recirculating cooling systems are not assessed or result in an unsafe use, direct discharge to surface water should be assessed also for small open recirculating cooling systems.

7. Technical and guidance related issues

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

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

Concerning open items not yet taken over by any AHEE members (point 2), SECR proposed a prioritisation of these items (priority indicated in colours: high = red, yellow = medium, green = low; prioritisation based on the time lines provided in Annex III of the RPR)

Concerning items that came up during product authorisation (point 3), the WG members agreed on the following procedure: the CA who initiated the e-consultation on a specific item should prepare the summary and conclusion of the consultation which will then be presented by the CA at the subsequent WG meeting for information (not for re-discussion or agreement). If relevant, it will be noted in the minutes of the respective WG meeting if the conclusion should be reflected in the TAB or if further actions are required.

Action SECR: to remind CAs on the procedure when initiating an e-consultation following a CA request.

The Chair further highlighted that any pending guidance related issues should be discussed preferably at WG-I-2017 and WG-II-2017. Deadline for providing documents for discussion/agreement at WG-I-2017 is **15 December 2016**. Starting from WG-III-2017 the focus will be on active substance discussions.

7.2 Agreement of documents discussed at AHEE-1

Items 7.2a – 7.2d comprise conclusions as well as revised documents coming from AHEE-1, which were send to the ENV WG for discussion and agreement (7.2a/7.2c) as well as for information (7.2.d):

7.2a Proposals for standard scenarios and parameter setting of the FOCUS groundwater scenarios when used in biocide exposure assessments for PT 8? (DE)

The ENV WG confirmed the conclusion of AHEE-1 that the application method "incorporation" and a soil depth of 5 cm should be used as default parameter settings in FOCUS groundwater models in case of manure/slurry application on grassland.

The ENV WG confirmed the conclusion of AHEE-1 that the standard scenario of manure/slurry application on grassland should not be modified, keeping in mind the comment by FI that application on the 01 March is prohibited in Finland, a limitation that needs to be considered during the product authorisation.

Conclusion: The WG agreed to add the conclusions of the AHEE to the TAB.

Action SECR: To prepare a **TAB** entry and to implement the AHEE-1 conclusions.

7.2b PT 18: Taking into account degradation in manure (NL)

The WG adopted the proposal in the document provided by NL. NL will prepare a summary document providing the input parameters and equations in a concise way.

Action: As a follow up, **DE/UK/ASO** to send further comments on minor issues to NL; to be taken into account in the final version. **NL** to check with SECR Table 1 of the document and to add some further text to the table for clarification.

7.2c Proposal on exposure assessment of metabolites in the terrestrial compartment (DE)

The following items have been discussed and concluded:

1.) *Do AHEE/ENV-WG-Members agree with a threshold of 75% for minimum parent degradation in a soil degradation study (referring to point A) 1)?*

Conclusion: The WG did not agree to the proposed threshold of 75%. It should be be decided by the eCA and discussed case by case if a study can be used to derive the input parameters for the metabolites.

2.) *In case no half-life for a metabolite can be derived, and QSAR estimations do not result in a classification of the metabolite as "not-persistent", should a default value of 1000 days be used or better 1 million days?*

Conclusion: A value of 1 million days (at 12 °C) as already included in EUSES should be used if no half-life for the metabolite can be derived from a study.

3.) *In case formation and degradation of a metabolite is observed in several soil studies, how to proceed?*

   a) *Use of geometric mean of the maximum peak occurrences, if more than 3 or 4 values are available? And use of the worst case if less studies are available?*
   b) *Use of geometric mean of the DegT50/DissT50 values, if more than 3 or 4 values are available? And use of the worst case if less studies are available?*
   c) *c) Combine worst case Fpeak.occurence / Ftransformed with worst case DT50 from different soil studies? If not, is Fpeak.occurence / Ftransformed or the DT50 prioritised as worst case?*
   d) *If the parameters could not be determined in each soil studied, should the missing values be replaced by default values (Fpeak.occurence /Ftransformed = 100 %, DT50 = 1000 days/1 million days) before a geometric mean is calculated?*

Conclusion: The WG preliminary concluded on b) to follow the same approach as for the parent. However it was concluded to follow up point 3 via an e-consultation.

Further open questions for the assessment of PECsoil,metabolite:

4.) *Do AHEE/ENV WG-Members agree to combine the DegT50 with the max. peak occurrence or should only the DissT50 be used?*

5.) *If only the DissT50 should be used, what shall be done in case a soil degradation study with the metabolite as analyte is done and a corresponding DegT50 is available?*

Conclusion: Points 4 and 5 will be followed up (as point 3) via an e-consultation.

Further open questions for the groundwater assessment (FOCUS PEARL):

6.) *Can the WG agree to the decision tree for the groundwater assessment?*

7.) *In case several metabolites need to be assessed, and no reliable formation fractions can be determined for all metabolites:*
   a) *Should an Ftransformed of 100% be assumed for those metabolites, for which no formation fraction could be derived (all relevant metabolites included in the transformation scheme)?*
   b) *Should each metabolite be modelled separately with its parent in FOCUS PEARL?*
   c) *Are there other possibilities?*

Conclusion: No conclusion was taken on points 6-7, the points will be added in the e-consultation on the previous points.

Action SECR: SECR to initiate the agreed e-consultation on points 3 to 7. If the results of the consultation is unambiguous, the document will be endorsed in a written procedure. If not, the item will be re-discussed at WG-II-2017 (to be decided after finalisation of e-consultation).

7.2d Update on the status of the draft guide on PT 21 product authorisation (UK)

UK provided an overview on the current status of the guide. The document will be scheduled for discussion at WG-I-2017.

7.3 Open items related to emission estimation in the frame of product authorisation (national/Union) (ECHA)

The SECR presented the discussion table where they have collected different questions coming from product authorisation (national and Union).

Items which have been concluded in the following will be added to the **TAB (Action SECR)**.

1. Use of the teat disinfectant products for other animals than cows

   - *Can the default values for cows be applied for other animals such as buffaloes, sheep and goats, since cows are considered the worst-case?*
   - *Should specific default values for buffaloes, sheep and goats be prepared (see also background)?*

   FR pointed out that when you have lower amount of nitrogen in your manure means that you can apply more manure on-land and therefore more emission which as contrary to the assumption made by the eCA.

   Some WG members commented that in general, buffaloes, sheep and goat is a minority cattle used for milk in comparison to cows.

   UK mentioned that they had done some research on buffalo, sheep and goats herds. In UK there aren't many herds for buffalo, sheep and goats but they've found a publication where the authors looked at 35 buffalo farms across Italy where in general they had 2

Kg of Nitrogen per m3 of manure which turns to approximately 40 % of the current dairy cow default values. Bearing in mind that buffalos are milked less often than cows (once a day compared to 2 or 3 for cows) the level of nitrogen which will result in amount of manure being applied to landfill almost balances out with cows. In regards to herd sizes they were not able to find more information. Therefore, they believe that cows can be considered representative for the other animal types.

NL commented that there is not a default value for volume applied for cow tit and normally the 10 ml for dipping and 15 ml for spraying is used. They would like to ask the WG weather to apply the default value or the information provided by the applicant. The SECR clarified that in case the applicant doesn't provide any further information the default value should be used (i.e. 10-15 ml).

Conclusion: The WG agreed to use cows as realistic case to cover also buffaloes, sheep and goats. The WG further agreed that for the time being no default values need to be prepared as follow up. If further information becomes available in the future this conclusion can be revised in the light of experience.

2. Use of natural background concentration as reference values for the risk assessment

- *Can a PEC/PNEC>1 be accepted as long as the corresponding PEC value is within the background concentration for a specific substance?*

The WG agreed that the decision should be made case by case as depends on the type of substance and the type of use. In general, the decision should be well explained. In general the recommendation done in the CAR should be followed for the product authorisation.

NL mentioned that background concentration should be used but not for the PNEC derivation as the exceedance of the background level changes the ecology of the system. Therefore the background concentration should be dealt with care.

DE also mentioned that a solutions should be provided before the active substance renewal. The SECR reminded the WG that the issue is listed in the pending issues for revision of the Vol IV Part B guidance but was not identified as a priority for this revision.

Conclusion: The WG agreed that this should be decided case by case, depending on the active substance following what was recommended in the CAR.

3. Treatment area for bait box scenarios

- *Which treatment area should be considered?*

Conclusion: The WG agreed to use a default area for the terrace of 30 m2 and assume a receiving area of 8.5 m2 (taking into account three sides of the terrace).
In addition a default value of 4 bait boxes should be used if no data on the application is provided by the applicant.

4. Fraction of product consumed by the ants vs. amount left at the bait station

- *What percentage of the product should be considered as entering the soil?*

Conclusion: The default values as provided in the ESD should not be changed, i.e. the risk assessment should be based on the remaining 20% entering the soil after flooding.

5. Groundwater as an environmental compartment potentially exposed

- *For outdoor application of insecticides in bait stations, should groundwater be assessed?*

Conclusion: Point closed. The WG agreed that for insecticides in bait stations a groundwater assessment should be performed on Tier I level in order to show that the exposure is negligible. If in the light of experience it is shown that the exposure is not negligible, a scenario for a Tier II assessment needs to be developed.

6. Groundwater as an environmental compartment potentially exposed

- *For outdoor application of insecticides in bait stations, should a risk assessment for the STP be performed (if urban areas are considered)?*

Conclusion: Point open. The point could not be concluded. As a follow up WG members on PT 18 are invited to provide open issues they have related to product authorisation in PT 18 (exposure assessment) to SECR by 15th of December.
WG members are invited to well formulate the issue and also to propose a prioritisation if several issues are provided.

Action SECR: SECR will screen the items provided by 15th of December and check if any items can be taken up in the PT 18 Expert Group meeting in January or if a dedicated workshop on PT 18 should be organised back to back with the March WG meeting.

7-12. Secondary poisoning related items

Conclusion: Points 7 to 11 open.

Action: DE will cross-check before mid of December if they are related to items that are covered in the revision of the ESD for PT 14. If yes, they will take up items 7, 9-11 in the frame of the revision of the ESD for PT 14.If this is not the case, the WG will be asked if the items should be taken up by the AHEE.

7.4 Precursors of in situ generated active substances (ECHA)

The SECR presented the changes introduced in the thought starter on this subject presented at the ENV WG-IV-2016 following an e-consultation launched after the WG-IV-2016 meeting.

The following four points were discussed:

1) *Does the WG agree with the proposed trigger of 0.1% for the precursors which is based on the concentration limit for significant impurities? Alternatively, either no trigger (according to Draft Guidance on Substances of Concern) or the lower metabolites trigger of 5% could be applied. Do you foresee any implications of a trigger for product authorisation?*

   Conclusion: Point open. Preliminary conclusion: The WG agreed to use a trigger value of 0.1% for the hazard assessment for unreacted pre-cursors and other non-active components of the substances generated in-situ beside the active substance and to use a trigger value of 5% (the lower value for metabolites) for performing a risk assessment.

   Action SECR: This item will be followed up via an e-consultation. The detailed discussion of this point at the WG meeting will be provided as well as comments received on alternative approaches during the first commenting round will be included in the e-consultation. WG members and ASOs will participate.

2) *Is mixture toxicity appropriately integrated in Figure 3?*

   Conclusion: Point closed. The WG agreed to the proposed Figure 3.

   Action SECR: More arrows will be added to make the Figure easier to read.

3) *Should catalysts be assessed? (the issue raised by NL through the APCP WG e-consultation)*

Conclusion: Point open. It was concluded that catalysts for the time being will be left out from the guide since further clarification is needed. Only a note will be included, reflecting the current discussion.

Action SECR: To follow up internally and then provide a proposal in the frame of an e-consultation.

4) *Do you overall agree with the proposal for risk assessment and information requirements for precursors of in situ generated active substances?*

Conclusion: Point closed. The WG agreed to the proposal for risk assessment and information requirements for precursors of in situ generated active substances in general. This excludes the points indicated as being open above.

7.5 Open TAB item on Freundlich isotherm for groundwater modelling (ECHA)

The WG agreed to the following text proposal to be included in the TAB:

The FOCUS models require the Freundlich adsorption coefficient (n) in order to determine sorption to soil of the active substance. The following three scenarios should be considered (in line with the approach applied for plant protection products):

1) The Applicant performs a full OECD 106 batch sorption study at multiple concentrations and derives reliable 1/n values. Here, the arithmetic mean[3] of the empiric 1/n values should be used in the FOCUS model.
2) The Applicant performs only the screening stage experiment of OECD 106, investigating sorption at a single concentration. Here, a default 1/n of 1 is to be used in any FOCUS modelling. This more conservative value is needed because of the lack of data on the relationship between the substance's sorption and concentration.[4]
3) The Applicant attempts to perform a full OECD 106 batch sorption study at multiple concentrations but it proves impossible to derive reliable n values. Here, a default 1/n of 0.9 is to be used in any FOCUS modelling. This value takes account of the Applicant's effort to derive empiric data for the relationship between the substance's sorption and concentration.

Action SECR: The agreed text will be added to the **TAB**. A note will be further added that if the guidance for PPP changes in the future, resulting in a change of the default value for the Freundlich adsorption coefficient, the TAB entry will be changed accordingly.

7.6 Status of the revision of Vol. IV Part B (ECHA)

SECR reported on what has been done since WG-IV-2015:

- The draft guidance has been amended with additional text proposals submitted after WG-IV-2016.
- The "product part" has been prepared utilising "Transitional guidance on mixture toxicity" and Draft guidance on Substances of Concern. The "product part" will be

[3] See http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4175/epdf (p. 31)

[4] See http://esdac.jrc.ec.europa.eu/public_path/projects_data/focus/gw/NewDocs/GenericGuidance2_2.pdf (p. 40)

integrated into the core document of Vol. IV Part B i.e. the guidance will cover both AS and BP.

- The "evaluation" (part C) will be added to the Vol. IV Part B (mostly only clarification to explain the difference between "assessment" and "evaluation").

PEG written consultation will be launched around 5/12/2016. The PEG meeting is scheduled for 16 March 2017. To be noted for PEG consultation: All comments are welcome, but only those will be addressed which relate to the areas identified for revision, any other comments will be addressed at next revisions of the guidance

7.7 Information on batches used in (eco) toxicity testing

SECR introduced the proposal to the WG. The WG welcomed the work done in putting together such proposal. FR asked for flexibility on the format of the table to accommodate t the differences on the impurities. DK mentioned that an extra column should be added to reflect if the tested batch is supported by the reference specification with a YES or NO. NL questioned if this only applies to UVCBs or to every compound and the SECR explained that it is designed for "regular" compounds and may be quite challenging to fill in for UVCBs or natural extracts with highly variable composition.

CEFIC made a number of comments in relation to the document:

1) What is meant by constituents? SECR indicated that, the definition and identification of constituents is under the remit of APCP and in this regard they follow the guidance on substance identification and naming under REACH.
2) There are test reports which do not contain chemical composition as it is confidential information, what to do then? The SECR explained that the applicant will need to provide the eCA with the information on composition of the batches used for ecotox testing. Most test reports contain the batch number of the material used and therefore the applicant should be able to retrieve chemical information on composition of the specific batches
3) There are very old studies where the information on composition is impossible to retrieve, what to do in these cases? The SECR explained that there is nothing that can be done on those cases and in order to assess the relevance of the material used in the testing, information on purity or manufacturing method should be used.

SECR will include the example tables in the CAR template including the comments made by MSCA.

8. AOB

8.1 Other information & lessons learned

SECR noted that the deadline for providing documents for WG-I-2017 meeting is 15 Dec 2016 and reminded authors to provide early feedback on if documents for guidance-related will be ready in time (i.e. after the draft agenda is provided), so that the number of WG meeting days can be adjusted accordingly. SECR also reminded on the instructions for closing points in the RCOM.

SECR informed that a letter was sent to the CA directors regarding reinforcement of the Ad hoc WGs with additional resources. This is due to the increasing number of exposure related issues identified in individual MSCAs, CG and WGs and since more issues expected to arise in the context of upcoming Union authorisations.

The working procedure and timelines for Union authorisation are available on the ECHA webpage.

SECR reported on the current guidance development related issues. For endocrine disrupters a joint guidance will be prepared by ECHA and EFSA (PEG and MSCA commenting in 2017). Guidance update on technical equivalence is foreseen to be started in 2017.

A combined CAR and CLH template is currently in the final commenting period by BPC, RAC and CARACAL. Publication is expected in February 2017.

Feedback was provided on the status of active substances in PBT Expert Group and on a science research project on the EPM approach.

As a follow-up from WG-IV-2016, SECR asked feedback from the WG members on the arrangement of e-consultations and ad hoc follow-ups with regard to announcement and timing of different follow-ups. WG preferred that ad hoc follow-ups can be run with different timelines as has been done so far and there is no need to run the follow-ups in parallel. The WG members confirmed to receive automatic messages from S-CIRCABC but preferred to receive the launching emails as well to better draw attention to the initiated follow-ups. In addition, periodic summaries of the on-going follow-ups were welcomed for status updates.

SECR is currently working on harmonizing the ad hoc follow up approaches between WGs since different procedures have evolved in the four WGs in order to avoid confusion.

As follow up of WG-IV-2016, SECR provided alternative approaches on how the TE-Tier II and/or test-batch related items should be handled at WG meeting level. DK noted that it is important to discuss items related to Technical Equivalence Tier II assessments. The WG members agreed on the following way forward: open items should preferably be discussed in an e-consultation (including several commenting steps as necessary). Only if it is not possible to come to agreement in the frame of the e-consultation, the point can be brought to a WG meeting for discussion.

8.2 Feedback from the EMA visit in June 2016

SECR visited the European Medicines Agency on 21-23 June 2016 and participated in the meeting of EMA's Environmental Risk Assessment Working Party (ERAWP) as well as in the Workshop on environmental risk assessments of veterinary medicines for use in aquaculture. The aims of the visit were:

- To exchange on the approaches for emission estimation of biocides in PT 3/PT 18 and veterinary medicinal products (VMP), which are applied in similar ways;
- To evaluate the possibilities for simplification of the emission scenarios for biocides, based on the approaches used for VMPs;
- To evaluate the possibilities for a collaboration in the development of an emission scenario for disinfection in aquaculture (PT 3) which is currently missing.

Comparative calculations for two active substances used as teat dips will be performed in Q1 2017 using the emission scenarios for biocides and VMPs. Based on the outcome, ECHA will initiate further discussions in the ENV WG.

The emission scenario for disinfection in aquaculture (PT 3) will be further discussed with the AHEE / ENV WG at WG-I-2017. In the frame of the disinfection project further information on the use of biocides in aquaculture was collected and draft scenarios have been prepared. The results will be presented at WG-I-2017.

DK and NO volunteered to provide support or at least available information to further develop these emission scenarios.

Action SECR: To set up a newsgroup to collect national information on disinfectants used in aquaculture.

8.3 Feedback from BPC on questions raised by ENV WG / AHEE

SECR presented the document and the conclusions taken at BPC-17 on the following four items referred to the BPC by the ENV WG and AHEE:

1) *RMM for PT 21 - AHEE-1 (item 6.1) / WG-III-2016 (item 6.7)*

BPC was questioned how the conditions in the RMM for PT 21 are linked.

Conclusions BPC: It should be 1 and (2 or 3). For further clarification the text of the RMM should be reworded in the future as follows: „…that application, maintenance and repair activities shall (1) be conducted within a contained area to prevent losses and minimize emissions to the environment, meaning (2) on an impermeable hard standing with bunding or (3) on soil covered with an impermeable material. Any losses or waste containing [the substance] shall be collected for reuse or disposal"

The meaning of contained area was further discussed, specifically if it includes wind protection.

Conclusions BPC: It needs to be further specified between the boat type and the application method: For pleasure crafts in case the antifouling is applied by brushing, wind protection is not relevant. For commercial ships in case the antifouling is applied by spraying, it may be relevant. This should be reflected in the PT 21 product manual currently under preparation by UK. It was further noted that wind protection should not be as such part of the standard RMM, but if needed during product authorisation (to be followed up by CG), it could be added as second provision. If identified as being relevant during product authorisation, also the release pathway via air should be covered by an emission scenario to be developed (AHEE). As overall conclusion, at this point in time the standard condition currently available should not be changed.

2) *RMM for PT 8 - AHEE-1 (item 6.1) / WG-III-2016 (item 6.7)*

BPC was questioned how the conditions in the RMM for PT 8 are linked.

Conclusions BPC: The following revised proposal for the RMM text was agreed: "... and that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal".

It was further noted that there are new alternative methodologies under development (e.g. covering the ground with adsorbing materials), however for the time being they will not be reflected in the RMM.

3) *Wood treated with short term antisapstain - WG-III-2016 (item 6.7)*

BPC was questioned if wood treated with a short term antisapstain still falls under the BPR and if it would be acceptable for these substances to assess only emissions during the storage period but not any emissions during service life.

Conclusions BPC: The short term antisapstain treatment falls under the scope of the BPR. The question on if it is a treated article can be taken up by the CA meeting, SECR will consult with COM on this aspect. If there is proof that there is no leaching of the antisapstain and/or that it is no longer efficacious, no assessment of the service life needs to be performed.

It was further noted that there is the need to develop as specific emission scenario for this kind of treatments in the future (AHEE).

4) *Collection of tonnage data (EU/national) to determine a reference tonnage for deriving a market penetration factor - AHEE-1 (item 5.4)*

BPC was questioned if the collection of tonnage data is in the remit of the BPC or if the item should be escalated to the CA meeting and if the BPC supports to start systematically the collection of tonnage data on EU/national level.

Conclusions BPC: Collection of tonnage data (preferably via a centralised system) was as such supported by the BPC members, however since the items is not in the scope of the BPC, it should be forwarded to the CA meeting.

Action SECR:

- Ad 1: Include the BPC conclusions (1a and 1b) on RMM for PT 21 in the TAB. Item 1b to be forwarded to UK.
- Ad 2: Include the BPC conclusions on RMM for PT 8 in the TAB.
- Ad 3: Include the BPC conclusions on the wood treated with short term antisapstain in the TAB and to send the item to AHEE for development of emission scenario.
- Ad 4: Continue working with recommendations for Fpen (item sent to CA meeting)

8.4 Possibilities to lighten the environmental exposure assessment

SECR presented a thought starter document to take up again the discussion on possibilities to lighten the exposure assessment and to spare resources since the workload for AHEE is constantly increasing. It was also noted that the exposure assessment for biocides is relatively complex compared to other legislations.

SECR invited the WG to provide ideas to simplify the exposure assessment. The initiative was welcomed by the WG but it was noted that care should be taken that by lightening the at active substance assessment the work will not be transferred to the product authorisation stage. As an example, proposal from DK was to apply RMM for some a.s./PT already at the active substance approval, especially for industrial uses.

Action: SECR to initiate an e-consultation to collect proposals for lightening the assessment at active substance approval stage as well as product authorisation stage.

8.5 Template Weight of Evidence approach for commenting

In general the propiosal was well received. Some MS asked for which section of the CAR it showlld be used. SECR clarified that the approach can be used for any endpoint where there are different sources of information and the eCA needs to decide on a specific value.

SECR informed that the checklists for accordance check for the different WGs are being finalised and will then be combined as one file. The eCAs will be asked to provide the checklist filled in together with the submission of the CAR.

Appendices:

Appendix 1:

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

Note:

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

No.	Title (current leader)	Status
		DE prepared a proposal based on the work done so far by UK and included comments from the former SoC-WG, which was send to DK for a first commenting. DE included comments from DK into the guidance. Endorsement by written procedure was initiated on 10 June with a deadline for commenting until 29 July, comments were provided from FR, NL, UK, CH. DE provided an updated version together with an RCOM table on 25 August 2016. **SECR included the revised version prepared by DE in Vol. IV Part B (biocidal product), to be further processed by the PEG.**
1.6	2nd EU Leaching Workshop for PT 8 (**ECHA**)	*Reminder:* ***Members*:** Start to perform a risk assessment for the new TIME2 (= 365 d), however not using it for decision making. Send the risk assessment to SECR via CIRCABC. ***SECR*** opened a Newsgroup on CIRCABC[5] in order to collect the data and perform an impact assessment as soon as sufficient data is available (target: in one year). **SECR** to include additional time also in the Excel sheet for PT 8 currently under preparation.
1.7	Fish net scenario (**ECHA**): discussion on the usefulness of the new version of MAMPEC to be initiated	Discussion was started by NO. **Possible inclusion in MAMPEC discussed with Deltares at AHEE-1, funding to be clarified by SECR (=> most likely in 2017)**.
1.8	1st revision of Vol. IV Part B (active substance) (**ECHA**)	1st revision: definition of subjects for first revision and assignment of volunteers taking over the subjects were agreed at WG-I-2016, revised text parts have been provided by 15 June 2016. After discussion of some items at WG-IV-2016. The draft document for the PEG consultation is currently under preparation (formal check ongoing) **Discussion of the revised text will take place in the frame of the PEG.**
1.9	Guidance on aggregated exposure assessment (**DE**)	The discussion of the draft guidance is re-scheduled for an electronic procedure, **to be started in Q4 2016**.
1.10	TAB (**ECHA**): Technical Agreements on Biocides	The second revision of the TAB was initiated, version 1.2 will be distributed in Q1 2017 for a six week commenting period.
1.11	ESD for PT 6 (**DE**)	DE has revised the ESD following comments received. **The ESD is scheduled for discussion at WG-I-2017.**
1.12	Guidance on disinfectant by-products (Dedicated WG)	The PEG written consultation is concluded, the CA consultation is planned to be launched on 19 September (4 weeks for commenting). **Publication foreseen in December 2016.**

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

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

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

No.	Title (current leader)	Status
ASSIGEND ITEMS		
2.1	How to use market share data in order to derive a market penetration factor different from default values? ⇨ *WG-I-2015 – item 6.2 + WG-II-2015 – item 7.3 WG-II-2014 – item 6.4 (pulp and paper processing fluids)*	AHEE consultation ended on 28 August 2015. Based on the comments received the proposal will be revised and then re-commented/confirmed by AHEE. A discussion of specific items took place at WG-IV-2015 and at AHEE-1. **One item (collection of tonnage data) was discussed at BPC-17. Revised recommendation will be send to AHEE in Q1 for commenting, endorsement of revised recommendation by ENV WG scheduled for WG-II-2017.**
2.2	PT 2, 3, 4: Preparation of specific scenarios for RTU - small scale applications ⇨ *WG-III-2015 – item 7.3*	ECHA contracted out the preparation of scenarios. **Following the e-consultation post WG-IV-2016, the proposed amendments will be discussed at WG-I-2017.**
2.3	PT 18: Development of equations to take into account degradation in manure ⇨ *WG-V-2015 – item 7.2b*	NL volunteered to take over this point. **Discussion at AHEE-1, NL will provide revised document to SECR by 1 July 2016. Endorsement scheduled for WG-V-2016.**
2.4	Clarification on DT50 values according to the FOCUS guidance to be used for modelling purpose and as trigger value (for higher tier studies/PBT assessment) ⇨ *WG-I-2016 – item 6.3b*	**DE/UK** volunteered to take over the item (update of PBT guidance to be taken into account). Timing to be defined.
2.5	Proposal on exposure assessment of metabolites in the terrestrial compartment ⇨ *WG-II-2016 – item 6.4*	DE will prepare a proposal for discussion. **Discussion at AHEE-1, endorsement scheduled for WG-V-2016.**
2.6	PT 2: Conversion of surface area to volume when applying the b.p. by e.g. vaporizing or fogging ⇨ *WG-IV-2016 – item 7.3*	ECHA contracted out the preparation of a first proposal.
2.7	PT 3: Scenario for disinfection in aquaculture	ECHA contracted out the preparation of a first proposal.

No.	Title (current leader)	Status
	⇨ *Disinfection project/EMA visit*	
2.8	PT 21: How to use data on background concentrations in the env. risk assessment ⇒ *WG-IV-2015 – item 6.3 (reference below the DTs to the respective RCOM table entries)*	FR volunteered to take over the item. Timing to be defined.
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)		
2.9	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.
2.10	PT 8: Use of a standard transfer factor (38 or 40) for transferring an application rate per volume to an application rate per surface (leaching rate assuming 100% leaching) or use of a specific transfer factor based on the dimensions of wooden commodity per scenario (of OECD ESD PT 8). ⇒ *WG-IV-2015 – item 6.2*	AHEE member to take over item to be assigned.
2.11	PT 6: Development of an emission scenario for the preservation of unrefined fuels ⇒ *WG-V-2015 – item 7.3*	AHEE member to take over item to be assigned
2.12	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.
2.13	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.
2.14	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.
2.15	PT 21: AHEE consultation - consideration of the PT8 ESD for accumulation and degradation processes (equation 3.11), and the	SECR to initiate.

No.	Title (current leader)	Status
	emission pattern for soil exposure (batch-wise vs. continuous release). ⇨ *WG-III-2016 – item 6.4 (AHF)*	
2.16	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.
2.17	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.
2.18	PT 7: Revision of the ESD (inclusion of the formulation step, alignment of equations with A/B tables) ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.19	PT 9: Definition/revision of fixation factors for PT 9 – leather applications ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.20	PT 18: Area of animal housing to be considered for applications in PT 18 ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.21	PT 18: Land application interval and manure storage period in PT 18 ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.22	PT 10: Removal processes ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.23	PT 9: Concentration in soil in PT 9 rubber-roof membrane scenario ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.24	Focus SWASH: Use of the model for calculation of PEC in sediment (PT 3, run-off from soil) ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.

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

No.	Title (current leader)	Status
3.1	PT 18: Consultation on ESD PT 18 (household + professional uses) - bait box scenarios (**NL**)	Questions raised by NL in the frame of MR, consultation initiated on 15 September 2016. Comments have been received from DE and FR. **Questions were included to item 7.3 of WG-V-2016.**
3.2	PT 18: Clarification of areas to be considered for wet cleaning (**UK**)	Deadline for commenting was 21 October 2016, comments have been received from CH, FR, DE, PL, DK.
3.3	PT 4: New emission scenarios for DBNPA (**DK**)	Deadline for commenting was 4 November 2016, comments have been provided by NL, DE, FR, UK.
3.4	PT 18: Market data for refinement of the exposure assessment (**DE**)	Deadline for commenting is 30 November 2016.

List of Attendees (Annex I)

Analytical methods and physico-chemical properties WG

Core members
MŰHLE Ulrike (DE) - Rapporteur
SIX Thérèse (FR)
HUIZING Tjaart-Jan (NL)
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WARBURTON Anthony (UK)
MARAGKOU Niki (EL) – alternate member
Flexible members
KORKOLAINEN Tapio (FI)
KARHI Kimmo (FI)
CATALDI Lucilla (IT)
GOUR Annabelle (FR) Rapporteur
AUBIN Aurélie (FR)
Stakeholders
MIHAI Camelia (CEFIC)
RANGGASAMI Nirmala (CEFIC expert)

Applicants
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MYÖHÄNEN Kirsi
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DAMSTEN Micaela
CIOATA Nadia
Applicants
Lonza
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Stakeholders
MIHAI Camelia (CEFIC)
COREA Namali – CEFIC (only for non-confidential items)

Efficacy WG

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HAMEL Darka (HR)
GIATROPOULOS Athanasios (EL) - Webex
DUH Darja (SI) - Webex
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MIHAI Camelia - CEFIC
ASHWORTH David – CEFIC expert

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GUTIERREZ Simon
SCHAKIR Yasmin
WEBER Jan