WG-II-2017

Final minutes

16 March 2017

Minutes of WG-II-2017

7-15 March 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-II-2017 (7 March 2017)

1. Welcome and apologies

The Chair welcomed the participants of the working group meeting. CEFIC and the European Association of chemical distributors (FECC) were registered as accredited stakeholder organisations (ASO) for this meeting.

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

2. Administrative issue

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

3. Agreement of the agenda

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

The following items were added to the agenda:

- Iodite used in biocidal products
- Content of certificates of analysis (CoA)
- Peracetic acid generated in situ; storage stability of precursors

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 I 2017

Comments on the draft minutes were received as follows:

Imiprothrin: France

The draft minutes have been updated accordingly and the working group members agreed on the modifications. The other parts of the minutes have also been agreed.

6. Follow up of previous working group meetings

6.1 Follow-up of previous working groups

- Icaridin

The working group members were informed that an e-consultation was held for agreeing on the reference specification based on quality control data that was provided by the applicant

to the eCA. The reference specification was adjusted accordingly and the reference specification was agreed.

7. Discussion on the active substances

7.1 Reaction products from paraformaldehyde and 2-hydroxypropylamine (ratio of 3:2; MBO) PT 02, 06, 11, 12 and 13

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

7.2 Reaction products from paraformaldehyde and 2-hydroxypropylamine (ratio of 1:1; HPT) PT 02, 06, 11 and 13

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

7.3 Cyphenothrin PT18

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

8. Technical and scientific issues

8.1 Accelerated storage stability

The e-consultation that raised different issues on accelerated storage stability and the comments received were discussed. The results of the discussion and the agreements are summarised:

- The accelerated storage stability test under test conditions is negative but no complete shelf-life study is available:
    - An accelerated storage stability test at lower temperature can be provided by the applicant. In case the test is acceptable, a lower storage temperature shall be indicated on the label.
    - Further information and tests can be provided by the applicant for demonstrating that the biocidal product is still efficacious and the degradation products are not impacting the hazard and risk characterisation of the biocidal product.

A provisional product authorisation can be issued if one of the above mentioned options is fulfilled. The provisional authorisation, which should be based on intermediate data from the two years shelf life study, can be granted up to two years or until the complete shelf life study has been evaluated.

- In case the degradation of the active substance exceeds 10 % in the accelerated storage stability test and no longterm storage stability test or another acceptable accelerated storage test is available, degradation products have to be identified and quantified. The hazard and risks have to be assessed for degradation products.

- The Manual on development and use of FAO and WHO specifications for pesticides states a 5 % threshold for degradation, whereas a 10 % threshold for degradation was agreed and applied previously under the BPD. It was agreed that the 10 % threshold should also be applied under the BPR.

8.2 Redefinition of Glucoprotamin

The working group members discussed the redefinition of Glucoprotamin as proposed by the eCA. It was concluded that the working group members did not agree on the redefinition of the substance, hence the substance name remains unchanged as 'Reaction products of glutamic acid and N-(C_{12-14}-alkyl)propylenediamine'.

8.3 Commodity Chemicals

A brief discussion about the meaning and the purpose of a document provided by a stakeholder organisation took place questioning whether commodity chemicals would require a specific treatment compared to other types of substances. The working group members were in complete agreement that the document does not provide sufficient and clear criteria on selecting substances as commodity chemicals. Further it was challenged whether a special treatment of commodity chemicals is actually needed as always sufficient information needs to be provided to characterise the composition of the substances and their identity. Therefore a special treatment of commodity chemicals is regarded as not appropriate and the mandatory information for substance identification shall be decided by the evaluating member state (eCA) on a case-by-case basis. However, the eCA shall initiate an e-consultation within the APCP working group members for agreeing whether the provided analytical information and results are sufficient to characterise the active substance. In case the working group members accept that reduced information is sufficient or an alternative approach for setting the reference specification is acceptable, this procedure is also to be followed if an application for the assessment of technical equivalence will be submitted to ECHA. Further, active substances supplied by alternative suppliers, listed on the Article 95 list, must be approved as technically equivalent. It is the responsibility of the applicant for biocidal product authorisation that the source is traceable.

No further discussion on the submitted document or in general on data requirements of commodity chemicals is expected.

9. Any other Business (AoB)

9.1 Update on Union Authorisation

ECHA provided an update of the received applications for Union Authorisation and invited the reference competent authorities (rCA) to present their experiences and issues of the received applications. A brief discussion took place on the further planning and possible organisation of the future working group meetings that will also include discussions on Union Authorisation.

The other issued raised:

- Iodite used in biocidal products
- Content of certificates of analysis (CoA)
- Peracetic acid generated in situ; storage stability of precursors

could not be discussed at the meeting due to time constrains but will be followed up with e-consultations or discussions at a future working group meeting.

Minutes of Human Health WG-II-2017 (7-8 March 2017)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 19 participants present, of which seven were core members and two alternate core members. Two stakeholder observers were present, one for all agenda items and one for the non-confidential agenda items. Applicants were registered for their specific substance discussions.

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

2. Administrative issue

SECR gave a brief presentation on housekeeping and administrative issues. The WG members were informed that R4BP 3 should be used for communication (First Draft CARs); the "Submissions" folder in S-CIRCABC will not be available for this purpose after the process flow 19 (18 March 2017).

The SECR explained that the file naming in S-CIRCABC will be streamlined in the following manner: Folder/Space name – "Draft CAR" (including sub-spaces "Draft CAR_v1", "Draft CAR_v2" etc.) and the folder/space name "Final CAR" should include only last final version of the CAR – the change will be reflected in the Biocides Active Substances IG structure.

3. Agreement of the agenda

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

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-I -2017

The minutes were agreed with minor changes.

6. Discussion on the active substances

6.1 MBO (eCA AT) PT 2, 6, 11, 12 and 13

The discussion points mainly concerned the reference values derivation and read-across to formaldehyde, as well as human exposure assessment. All points were closed.

6.2 HPT (eCA AT) PT 2, 6, 11 and 13

The discussion points mainly concerned the reference values derivation and read-across to formaldehyde, as well as human exposure assessment. All points were closed.

6.3 Cyphenothrin (eCA EL) PT 18

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

7. Technical and scientific issues

7.1 Update on guidance development

SECR indicated that the general guidance structure for biocides has been changed to indicate that for human health, the guidance consists of Part A *Information requirements* and Part B+C *Assessment + evaluation*. The new structure is shown at the ECHA website: https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation.

A paragraph will be added to the Preface of all Biocides Guidance documents, with links to the BPC document[1] "*Applicability time of new guidance and guidance-related documents in active substance approval* " and the CA meeting document[2] "*Relevance of new guidance becoming available during the process of authorisation and mutual recognition of authorisations of biocidal products*". These changes will be made by corrigenda and published by April/May 2017.

The revision of the guidance on technical equivalence has started and a new draft is expected to be available during 2017.

SECR will provide the next version of TAB during the first quarter of 2017. No input from the members has been provided.

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

SECR informed on the recommendations available on the HEAdhoc website[3] and on the recommendations and projects currently under preparation or consolidation by the HEAdhoc.

The HEAdhoc recommendation 6 has been updated to version 3 to address the latest agreements within HEAdhoc. The scenarios related to professional teat disinfection (PT 3) have been removed as they are now described in HEAdhoc Recommendation 13.

HEEG Opinion 17 - Default human factor values for use in exposure assessments for biocidal products has been revised and converted to a HEAdhoc recommendation. It was agreed to be circulated to HEAdhoc members and stakeholders for their check before scheduling it for discussion at WG-III-2017.

A member requested to correct the published HEAdhoc Recommendation 13 regarding the units for the room size. The proposed change will be checked by the SECR and the member and was agreed to be circulated to HEAdhoc members for transparency.

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

SECR informed that the PEG on "*Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses*" has been launched in March. The finalisation of the document is foreseen by September 2017. The "*Guidance on estimating livestock exposure to active substance used in biocidal product*" will be finalised following CA consultation by July 2017, pending the agreement on the teat disinfection scenario. The "*Guidance on estimating transfer of biocidal active substance into foods – professional*

[1] https://echa.europa.eu/documents/10162/4221979/applicability_guidance_jan_16_en.pdf/0b9c0634-eb54-4805-8b5e-b95f09a05632

[2] Path: /CircaBC/SANTE/BPR - Public/Library/documents_finalised/CA-July12-Doc.6.2.d - Relevance of new guidance.doc; https://circabc.europa.eu/w/browse/03bce60b-cf04-49aa-8172-e9c6a75205a7

[3] https://echa.europa.eu/view-article/-/journal_content/title/recommendations-of-the-ad-hoc-working-group-on-human-exposure

exposure" is still on hold until an agreement on the CA-March17-Doc.7.6.a document is reached.

7.4 WG discussions on issues related to classification and labelling

SECR presented the document proposing how open comments should be dealt with when they concern classification and labelling (C&L). According to the proposal, the WG would abstain from discussing C&L, and the questions for the WG should then concern only the establishment of the NOAEL/LOAEL and NOAEC/LOAEC, as well as the possible need for an additional assessment factor due to e.g. overall uncertainty, nature of the effect or duration extrapolation.

The members generally supported the proposed approach, pointing out some necessary clarifications and additions. Several members argued that a conclusion on the need to perform local risk characterisation has to be made, and this will depend on the C&L of the product and consequently also the C&L of the active substance.

It was clarified that the proposal to abstain from discussing C&L concerns only C&L itself and therefore the WG would still be expected to discuss all toxicological effects.

The members also referred to a possible need to have a harmonised approach for the different WGs.

SECR clarified that WG conclusions will not be expected on the fulfilment of exclusion criteria, as for human health, these are based on C&L that has to be available before the CAR can be submitted[4].

It was proposed that the comments regarding C&L should not be marked as closed, as this could suggest that the issue is solved, and instead an alternative wording could be used.

SECR will provide a revised document for commenting by the MSCAs and Associated Stakeholder Organisations and will inform on the timelines by e-mail.

7.5 Data requirements for precursors of *in situ* generated active substances

SECR had provided two written questions for the WG members' consideration.

Question 1.

> *"According to the competent authority meeting document (CA-Nov15-Doc.5.5 Final_Rev 1), only the properties of the in situ generated active substance are considered to define whether the exclusion, substitution and Annex I listing criteria are met during the approval process. Human exposure can however take place to all constituents of the substance generated in situ, and therefore one might consider that from the scientific/technical point of view, the substance generated in situ should be considered, comprising the active substance, (unreacted) precursors, reaction by-products and other impurities. SECR invites the MSCAs to provide their views on this."*

SECR clarified that any consideration of the WG could not overrule the CA meeting agreement and the input was requested in order to clarify whether there could be the need to clarify the CA meeting agreement.

The members considered that, as for any other active substance, it is necessary to demonstrate that a safe use can be identified. This would only be possible if the *in situ* generation can take place without having e.g. carcinogenic or mutagenic substances, reproductive toxicants or endocrine disruptors in the substance generated *in situ*. The WG broadly supported the view that from the technical and scientific point of view, the whole substance generated *in situ* should be taken into account in determining the fulfilment of the exclusion, substitution and Annex I listing criteria.

[4] Post-WG note: WG conclusions will however be expected on endocrine disruption (ED) once the ED criteria are available and applicable.

Question 2.

> *"The CA meeting document CA-Nov15-Doc.5.5 Final_Rev 1 states the following: "It has been agreed that the decision on the approval would refer to the in situ generated active substance together with the supported precursor(s) from which the active substance is generated, including when relevant the generation method." With this background, it appears necessary to clarify to what extent the precursors should be assessed at the active substance approval stage, taking into account the subsequent assessment of the precursors for the product authorisation. The WG members are therefore invited to discuss the purpose and extent of the assessment of precursors at the active substance approval stage."*

The members were of the view that the assessment of precursors should also be done at the active substance approval stage, as this would ensure a harmonised assessment. This would furthermore ensure that a safe use can be demonstrated, as this would not necessarily be possible for the *in situ* generated active substance without full consideration of precursors. At product authorisation, it will be necessary to take into consideration any additional co-formulants that may not have been assessed during active substance approval.

Other input on the document

The members supported the principles as given in the document.

One member commented that the minimum purity of the precursors, as well as maximum impurities of the substance generated *in situ* should be determined. In general the WG members agreed, but this was considered up to the APCP WG to conclude. The documents of the different WGs will be put together once they are agreed.

The relevance of chapter 3.1 *Substance generated in situ* was discussed, as the document should focus on precursors. It was agreed that the chapter is relevant due to the need to perform a risk assessment to the substance generated *in situ*, comprising also precursors. This explanation will be included in the document.

Based on all the input provided, SECR will provide a revised document for commenting, and will inform the members and associated stakeholder organisations accordingly.

7.6 Consumer exposure to iodine residues in milk due to teat disinfection

In a closed session, the WG discussed generic issues related to consumer exposure to iodine residues in milk due to teat disinfection. Please refer to confidential minutes for details.

7.7 Product residues from paper used for food/feed packaging (PT 12)

SECR presented the document to be discussed asking whether the assessment of residue transfer to food/feed is relevant for PT 12 in general. The majority of the members agreed that the conclusion of the WG-IV-2016 should be considered specific to the substance under discussion at that time. The members indicated that the experience gained so far with dietary risk assessment for PT 12 products is rather limited and would not be sufficient to conclude that dietary RA is not relevant for PT 12 products; moreover, it was proposed that estimation of the residue transfer to food and feed should always be performed. One member was of the opinion that for PT 12 products, the transfer from packaging to food/feed is minimal and therefore not relevant for dietary risk assessment.

SECR will provide a revised version of the document for commenting.

7.8 Information on batches used in toxicity testing

SECR presented the document that had been only slightly revised following the first discussion at WG-V-2016 and written comments from CEFIC.

One member pointed out that a thorough analysis of all batches may be very difficult, noting the long history for many substances, with lots of different batches used in testing and the test batches having been analysed for different components using various analytical methods

and detection limits over the years. SECR clarified that the intention of the table is not to create further information requirements but to report the information that is available for each batch.

The members supported the document as it was provided. One member will provide a proposal for a footnote to the table that will then be considered by SECR.

8. Any other Business (AoB)

8.1 Update on Union Authorisation

Updates on Union authorisation were given by the SECR and evaluating MSCAs to present an overview of the current status of the applications submitted so far and an outline of the ongoing activities. SECR presented a proposal about the planning for the discussion at the Working Group and BPC meetings of the first applications expected to enter the peer-review phase in 2017.

The document "Discussions and issues concerning Union authorisation expected at Working Groups and Biocidal Product Committee meetings" aims at highlighting potential issues that might be raised during the discussions at the Working Group and BPC meetings. It is considered as a living document that can be updated as experience is gained in the peer-review of Union authorisation applications. The WG members may provide any further input on the document by contacting the functional mailbox BPC-WGs@echa.europa.eu. The document is available to MSCAs in S-CIRCABC:

- Path: /CircaBC/echa/BPC-WG/Library/Confidential/06. Common issues/Union authorisation
- https://webgate.ec.europa.eu/echa-scircabc/w/browse/6e6b8ac4-2e9b-43d3-b082-56da5ebe50ad

8.2 Other information & lessons learned

Scientific topics to be elaborated for the Human Health WG

SECR presented the document where a list of topics was included that would need to be elaborated in order to discuss them at the WG. Any member could inform the SECR of their willingness to develop a document for WG discussion, and any further input with regard to additional topics was welcomed. Any input should be provided by e-mail to SECR, except for confidential information that should be provided via S-CIRCABC or R4BP 3, as appropriate, always informing SECR by e-mail as well.

It is foreseen that an updated document is provided for each WG meeting.

Template for reference value information

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

Dermal absorption of anticoagulant rodenticides from formulations

SECR informed that the collection of information was launched 8 February 2017. Information had been provided by three MSCAs. Conclusions on the possible derivation of reference values will be made at a later stage.

Combined CAR/CLH template

The template applicable for both CLH and biocides processes was commented by the members of BPC, RAC and CARACAL until 31 January 2017. Comments are currently being addressed and the responses to comments will be uploaded to S-CIRCABC. The final template will be made available in S-CIRCABC and on the ECHA website.

WG minutes

Some members have requested the WG minutes to indicate the members or MSCAs making comments at the WG meetings. Currently the minutes do not refer to individual members in order to protect their integrity as experts. Only the input from the evaluating Competent Authority is stated. The clear majority of the members preferred this approach.

The members making comments will thus not be indicated in the minutes of the Human Health WG, except if a member specifically requests including in the minutes his/her disagreement on a particular agreement.

One member expressed their wish to have minutes that are more extensive. SECR referred to a balance between too little and too much information, aiming in principle to have as brief minutes as possible while including all the argumentation. As a reaction, SECR intends to include some more details in the minutes.

Late comments

In recent active substance discussions, members have made some completely new proposals regarding e.g. reference value derivation. SECR explained that in such a situation, it is difficult to reach an agreement and even, if an agreement is reached, it could be questionable as the other members may not be familiar with the relevant studies and other information.

SECR therefore requested the members to indicate to the eCA and SECR their intention to make such proposals as early as possible, but at any time before the meeting. This would enable the eCA and SECR to prepare adequately for the discussion, and ensure that also the other members have access to the relevant information.

Minutes of Efficacy WG

WG-II-2017 (8-9 March 2017)

1. Welcome and apologies

The Chair welcomed all participants to the 16th Efficacy WG meeting. There were 5 core and 1 alternate member who participated in the meeting. In addition, 14 flexible members, and four ASO representatives (three experts only for the non-confidential agenda items) attended the EFF WG meeting.

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

2. Administrative issues

SECR gave a brief summary on the administrative issues.

3. Agreement of the agenda

The Chair introduced the agenda items. Members agreed on the proposed agenda. Additionally the Chair informed the EFF WG members that issues discussed under AOB and related to national authorisations should be now at the first instance solved between MSs. There are two ways forward. They can be addressed and discussed in the Coordination Group (CG), or in written form via e-consultation between the EFF WG members. If CG decides that discussion at WG level is needed, ECHA will be requested to include this issue into EFF WG agenda. Due to upcoming discussions on applications for Union authorisation the EFF WG will focus first of all on evaluation of active substances, guidance related issues and Union authorisations. Nonetheless, there is still a place to address general (horizontal) issues for discussion depending on the time availability.

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-I-2017

The Chair informed that comments for the minutes of WG-I-2017 had been received from DE, FR, NL and SE. Most of the comments have been accepted, except one made by the NL related to agenda item 8.3 and concerned bilateral discussion between ECHA and DE on the list of chemicals that are potentially active substances. This discussion was not foreseen for setting up the cut-off values and scientific justification as commented by the NL.

6. Discussion of active substances[5]

6.1 MBO (eCA AT)

There was one remaining open point concerning efficacy for discussion in the RCOM table, in which it was noted that for PT 11 efficacy against *Legionella pneumophila* (the most representative target organism for this area) should be shown. The eCA informed that a new efficacy study with *Legionella pneumophila* has been submitted. This point was left open, and an ad hoc follow-up will be launched.

6.2 HPT (eCA AT)

There were two remaining open points concerning efficacy for discussion in the RCOM table. The first open point concerned longer contact time needed as compared to the contact times stated in the EN standard methods used. The EFF WG agreed that longer contact time is

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

acceptable to prove cidal activity of the active substance. Additional data have to be submitted at product authorisation stage.

The second open point concerned the need to assess the product in a cooling water matrix. The EFF WG agreed that submitted studies are sufficient to prove innate activity of the active substance.

7. Technical and guidance related issues

7.1 Update on guidance development

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

- Vol II Part A - update to align with B+C: Drafting/revisions by WG in progress: no timetable yet for consultation process
- Vol II B+C update to Section 5/PT8 to add Appendix 4 on "Annex A of EN-599": Finalisation of drafting by WG due at March WG meeting; Update/consultation to start May/June by written procedure
- Vol II B+C update to PT5 following ECHA Disinfectants project: Drafting/revisions by WG in progress; Consultation planned for 2017
- Vol II B+C update to PT11/12 and PT19
- Drafting/revisions by WG in progress (PT11/12); Consultation planned for 2017

FR asked if after written procedure foreseen for Appendix 4 of PT8 efficacy guidance comments will be discussed again at EFF WG. ECHA informed that in case some very specific comments will be received the discussion at WG can take place again but the intention is rather to solve them bilaterally between ECHA and FR (EWPM). After adding Appendix to Vol. II/B+C a new version of this guidance will be published indicating the date of update.

The Chair informed that PT18/19 efficacy guidance will be sent for comments after the WG meeting and comments should be made to PT19 only.

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

FR presented the revised version of Appendix 4 prepared with support of EWPM. All editorial comments had been already accepted.

The following changes were discussed and agreed during the meeting:

- in section A.2.2. d and e the text "*It can be questioned if this restriction still has justification in cases where additional pigment can be shown not to affect penetration (as required in A.2.5).* " should be deleted.
- in section A.2.2. d and e the sentence " *It can be accepted to test a formulation without pigment.*" was modified. The new version was agreed "*It can be accepted to test a formulation without pigment. In cases where additional pigments are used in the product, it has to be demonstrated that the conditions of A.2.5 are fulfilled*."
- in section A.2.2. d and e the sentence "*Some pigments can reduce the penetration of the wood preservative into the wood*" was deleted in order not to repeat the same meaning already included in the text below.

The agreed version will be sent by ECHA for PEG consultation (written procedure).

7.3. PT11&PT12 matrix claim

FR presented a short update of the ongoing preparation of PT11&12 efficacy guidance. As post EFF WGI2017 discussion two separate claim matrices were prepared:

- first following the definitions of these PT's in the BPR - PT11 biocidal products are related to the preservation of the fluids and the PT12 products are related to the biofilms;
- second following the understanding of the IND - PT11 biocidal products are related to the cooling systems/process (including efficacy against biofilm biofilm as the formation of biofilm occurs also in cooling tower systems) and PT12 products are related to the paper and oilfield production.

To solve this issue related to the interpretation of the BPR provisions ECHA contacted COM and sent a request for clarification. Therefore, FR informed that for the time being the guidance development is on standby until the clarification by the COM will be given.

7.4. Interpretation of PT 8 efficacy guidance for use class 2

The points for discussion were referred to the EFF WG as an action point from the discussion in the CG-21 meeting and related to proper interpretation of PT8 efficacy guidance for Use Class (UC) 2.

The NL received PT8 applications for national authorisations for products containing permethrin as only active substance. As permethrin is an insecticide without any fungicidal activity, and in the applications the products are considered by the applicants for preventive use against insects (wood-destroying beetles/termites) in UC1 and 2 (sometimes also 3), a clarification of interpretation of PT8 guidance and EN 599-1 was requested by NL.

NL also questioned the companies' proposal to include the additional restriction in authorisation that such products must always be used together with a wood fungicide.

The outcome of the discussions from EFF WGII2017 is following:

Products used as wood preservatives with only one active substance without fungicidal activity – (permethrin in this case) considered for preventive use should be restricted only for UC1 in order to be in line with PT8 efficacy guidance and EN 599-1. Taking into account that wetting can occur at different degrees in accordance with EN 599-1 for UC2 and higher classes efficacy against brown rot fungi must be demonstrated as a minimal requirement.

It was also agreed that the use of insecticide product in combination with wood fungicides would not be acceptable way forward in order to authorise the product for UC2 or higher. Especially considering that the combination of products can have influence on the overall risk assessment.

Products (PT8) with only insecticide activity can be authorised for preventive use only in UC1. Moreover during the CG consultation FR proposed to add the following use instructions:" Only for situations in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting . In case where wetting can occur, even occasional, the product is not efficient against fungi and moulds". NL agreed for it.

The outcome of the EFF WG discussion was briefly presented in CG-22 by ECHA.

7.5. PT 5 Efficacy Guidance

The Chair introduced the open issues for PT 5 guidance, part of them remaining from the Disinfectants Project, part of them made by the EFF WG members during the commenting round.

Setting up criteria for secondary disinfection was discussed. The EFF WG concluded that the group lacks expertise to be able to set them up, and this issue will be flagged for PEG consultations. A requirement for a challenge test was added to secondary disinfection, to underline that it is more like preservative than disinfectant use.

Bacteriophages were removed from lists of target organisms, since they are part of viruses. The EFF WG concluded that the test organisms should be Enterovirus and either Adenovirus or Norovirus, but this will be verified in the PEG consultations. Specifications for test viruses were discussed (Adenovirus, Norovirus and Enterovirus types). NL will review which viruses

are used in CEN tests, and the requirements for test organisms will be flagged for PEG consultations.

The test conditions, contact time, temperature, and soiling were discussed for different use areas. Where EN phase 2, step 1 tests are mentioned, a specification “food area” was added. It was agreed to indicate 15°C as test temperature for all use areas, except for reservoirs and small scale water disinfectants. For most use areas a contact time of up to 25 min was agreed upon. The soiling of 2.5 mg/l DOC (not BSA) for drinking water suppliers and in-water distribution systems (Chapter 6.2), and 15 mg/l DOC for raw water for individual supply (Chapter 6.3) was proposed. The EFF WG concluded that for deciding for test conditions for reservoirs (Chapter 6.5) more expertise is needed, and this issue will be flagged for PEG consultations. It will also be flagged for PEG consultation whether simulated use tests or challenge tests should be required for reservoirs. For small scale use (Chapter 6.6) the EFF WG agreed that contact time should not exceed 30 min, and viruses should be added as required test organisms.

The Chair informed that Appendix 6 will not be included in the guidance, instead a link to the ‘Quantitative determination of the efficacy of drinking water disinfectants’ document will be added. DE will verify that BAuA has no objections of adding this reference to the guidance.

AISE questioned whether 100 cfu/l can be required as the norm value for *Legionella*, since this is the limit of detection for most test methods (Chapter 6.4.2.3.3 Field trials).

ECHA will implement the above changes and other changes agreed upon to the guidance document, which will subsequently be sent for PEG consultations. The Chair invited Cefic and AISE to spread the draft guidance to relevant persons in their organisations. The Chair will verify the possibility to appoint additional ASO representatives for the PEG meeting.

Actions needed:

- AISE to send further input on their comment on the *Legionella* limit of 100 cfu/l (under 6.4.2.3.3 Field trials);
- NL to check which virus types (Adenovirus type, Norovirus type, Enterovirus type) are included in the relevant CEN standards as test organisms;
- DE to check soiling conditions in chapter: 6.2/6.3 and sections: 6.4.2.3.2/6.5.2.3

8. AOB

8.1 ‘Service life’ claims made for PT 8 products

UK presented a question regarding service life claims made for PT 8 products. Based on current experience UK informed that the applicants do not necessarily want to claim long service life, but they are increasingly requesting that the service life of their products would be considered in the evaluation. UK thus wanted to initiate discussion on agreeing a harmonised EU position on service life, taking the British Standard “BS 8417 Preservation of wood. Code of practice” into consideration. An e-consultation on this issue had been launched in September 2016, with only a few answers received from MSs. Apart from those answers the EFF WG did not have much experience or knowledge of claims for service life. In general the EFF WG agreed that UK can authorise a service life claim, but for mutual recognition each MS may apply its own rules/procedures. It was also noted that it must be clearly indicated in the PAR that the service life claim is done in accordance with national rules/procedures.

8.2 Testing to prove that co-formulants are not an active

This issue was discussed in the past in the EFF WG (WG-V-2016 and WG-I-2017) and in the CEN WG5. Based on these discussions NL prepared a revised version (version 2) of the initial document, which was discussed in the EFF WG-II-2017. In this revised version three different tests are proposed, as a certain level of flexibility is needed; e.g. in case a formulation is unstable, or it is not possible to remove co-formulant from the formulation. It is up to the eCA to decide which test(s) should be performed by the applicant. All tests should be (modified) suspension tests (Phase 2 step 1) as they are well known, validated and deviations in results are very limited.

The EFF WG agreed that any deviations from a test method must be clearly described and justified. Such an information was added at the end of section A. Examples clarifying how to achieve a required concentration of the product in test 1 and the co-formulant in test 2 were moved to the footnotes.

It was also agreed that generally, these tests should be performed with bacteria, however other test organisms are acceptable, if they are more suitable. In such a case justification should be provided by the applicant.

The required lg reduction for co-formulants in a certain formulation should be at least 2 lg lower than the required lg reduction in the Phase 2 step 1 tests. The 2 lg reduction value is proposed by CEN WG5, and bacteria are recommended test organisms.

It was agreed to replace excipient by co-formulant as excipient is not defined in the BPR.

Actions needed:

1. Cefic to draft an example on interfering substances to part D (how to perform tests with proportionate amount of interfering substance);
2. FR to check with CEN the status of this document. The intention of the EFF WG is to publish it as a part of TAB;

The revised (but not yet finalised) version is attached below.

WGII2017_EFF_8.2_ Co-formulants_agre

8.3 Performance for algaecidal products with aesthetic claims (closed session)

The following questions raised by DE were discussed during the meeting:

1. *What kind of growth inhibition would be required for authorisation of the aesthetic claim products? Would MS mutually recognise algaestatic products with the inhibition percent 75%?*

   DE explained that so far there are no guidelines for aesthetic effect. Therefore, the number 75% is based on the initial discussions with some MSs for products with curative claim for which 75% might be the minimum acceptable percentage depending also from the use place.

   It was indicated by one member that 75% growth inhibition would be acceptable for them for MR procedure. One member would like to have more visual data as supporting information. For that DE indicated that this is not a curative treatment therefore, the visual conformation is not possible.

   One member informed that they had discussions with applicant regarding algaecide product for swimming pool. The test protocol for similarity use test was submitted and during e-consultation all MSs accepted the proposed efficacy criteria (5 days incubation - no growth observed) for swimming pools (algaecidal product).

2. *The efficacy calculated from OD (optical density) differs from the efficacy calculated from Chlorophyll a content (in some cases by a factor 3). DE questioned would MS agree always to take the lower efficacy value to have a "safety margin" or rather mean value would be more acceptable? The other possibility is to ask the applicant the justification which of the options would be more reliable.*

   In general, some EFF WG members were in the opinion that the justification for the discrepancies should be submitted by the applicant. It was also pointed out that during the e-consultation for algaecidal products both methods (OD measurements and Chlorophyll a calculations) were proposed as obligatory. Additionally, one member expressed the view that the worst case value should be used for efficacy evaluation.

3. *For which uses (pond, aquarium, fountain or swimming pool) would MS agree with simulated use tests (simulating a worst-case scenario)?*

There were no opinions expressed by the EFF WG members for this particular point.

4. *DE asked MS which volumes would have to be used in the simulated use tests for the different uses? Additionally DE questioned would be acceptable that tests in a 1 L/5 L volume under worst-case conditions is not sufficient to prove efficacy for use in ponds or swimming pools)?*

   It was pointed out that during e-consultations for swimming pools (algaecidal claim) the volume 100 to 200 litres in the simulated use test was recommended for test performance. One member expressed that smaller amount of water for testing should also be taken into consideration.

   Special concern was indicated by one MS in relation to the used volume in simulated tests for ponds as the different layers of water are applicable in life (for example, with the different level of oxygen, etc.).

5. *Pool: Would the EFF WG agree that in case that the algaestatic product is used in parallel with disinfectant (e.g. chlorine), or in pools with recirculating systems, that these circumstances would have to be simulated in the efficacy testing since they could negatively impact the efficacy of the algaestatic product?*

   It was pointed out that the chlorine has the algaecidal effect themselves and if the combination of active substances is used the result is not foreseen, can be with positive and negative effect. Therefore, the simulation test with chlorine is necessary.

6. *Pool: In case a soiling with BSA is not possible (BSA seems to disturb measurements and promote bacterial growth if testing takes several days to weeks), would the EFF WG agree to use BFA (body fluid analogues) as soiling, if a justification for the chosen BFA is provided by the applicant?*

   One member informed that they had similar situation with BSA and BFA soiling. The applicant needed to justify the similarity of the soiling used for providing the evidence why that is relevant for such case.

In addition it was mentioned during the discussion that there are no guidance/guidelines for aesthetic claim and it should be addressed in the future during revision of existing guidance.

8.4 Relationship of label and marketing claims

DE presented the idea to develop positive and/or negative list of label claims to be used by the applicants when draft SPC is prepared. There are ongoing discussions on regulatory issues for label claims in CA and CG meetings. However, DE pointed out that also the technical discussion is necessary.

Additionally it was mentioned that the different understanding of the “marketing” claims might be among MSs considering also the discrepancies of translation of the terms.

Two main questions were raised by DE:

1. *Which kind of label claims have MSs encountered so far and which ones did MSs accept and which ones did MSs refuse?*

The EFF WG members were in the opinion that only technical claims should be accepted in SPC, some of them noticed that at national level mixed and marketing claims are listed in the draft SPC. The discussion regarding of understanding of “mixed” label claim seems to be necessary in the future.

One member informed that they have a lot of marketing label claims which clarify the efficacy data for users. This should be also carefully considered in discussions.

2. *Do you agree with DE proposed way forward (e.g. the development of a “positive” and/or “negative” list of efficacy label claims)?*

In general the EFF WG members were in favour to prepare a positive/negative list as a non-exhaustive (living) list. It was not discussed which list should be prepared. Some concerns were raised in relation to organisational issues: (a) who will be in charge of this list? (b) where

it will be stored? (c) how it will be worded (d) how the common understanding of specific terms will be assured?

Taking into account that during CG discussion some of the MSs questioned the acceptability of such claims the Chair requested to ask first the MSs for their opinion and then to start work on such technical list(s). It was agreed that DE will raise this issue during the discussion on the revised version of doc. CA-March17-Doc.4.3 at CA meeting in order to have a common view whether such list is acceptable for all MSs.

8.5 TAB – proposal for inclusion

The NL revised slightly the initial proposal concerning disinfection of packaging before filling. Finally the EFF WG agreed that following data should be provided to demonstrate efficacy of a product for aseptic packaging applications:

1. Efficacy should be demonstrated by validation of the product in the disinfection process using aseptic filling devices and packaging material that are representative for the intended use of the product. Phase 2, step 1 and phase 2, step 2 tests are not required;
2. A negative control should be performed (with e.g. water) to demonstrate that the high temperature alone is insufficient to achieve sufficient control of microorganisms;
3. Products are efficacious under certain conditions, e.g. temperature, concentration, contact time, etc. Products can be tested in aseptic filling machines that meet/use the (worst-case) conditions for the product to be efficacious. The conditions to be taken into account include surface temperature, concentration, amount of product applied, contact time, relative humidity, dose and inner surface properties of the packaging;
4. All target organisms claimed should be tested in the negative control to demonstrate that they are killed by the test conditions. Therefore, demonstrating efficacy against bacterial spores (e.g. *Geobacillus stearothermophilus*) is sufficient for an efficacy claim against other groups of microorganisms for aseptic filling applications. Any target organisms surviving in the negative control should be tested by validation of the product in the disinfection process.

The result of this discussion will be included into the next update of TAB.

8.6 Update on Union Authorisation

An update on Union authorisation was given by ECHA to present: an overview of the current status of the applications submitted so far; an outline of the ongoing activities; and a proposal about the planning for the discussion at the Working Group and BPC meetings of the first applications expected to enter the peer-review phase in 2017.

In relation to the ongoing activities, ECHA explained that the document *"Discussions and issues concerning Union authorisation expected at Working Groups and Biocidal Product Committee meetings"* has been uploaded to S-CIRCABC in both the clean and track changes versions. The document aims at highlighting potential issues that might be raised during the discussions at the Working Group and BPC meetings and is considered as a living document which can be updated, while experience in the peer-review of Union authorisation applications is built up. In the long run, when expertise is consolidated, the document can be archived.

With reference to the planning about the applications estimated to enter the peer-review phase in 2017, ECHA indicated that, according to the records from R4BP 3, the applications for products containing iodine/PVP-iodine (PT 3 and PT4) and for products containing octanoic and decanoic acid (PT 4) are the first to be expected. ECHA highlighted that the timelines for the discussions at the WG and BPC meetings are still tentative and they might be subject to variations, depending on the ongoing discussions on the issues identified during the evaluation step. Nonetheless, ECHA pointed out to the possibility of organising an early Working Group discussion for products containing iodine/PVP-iodine during the WG-III-2017. A physical meeting was preferred by the WG members.

Concerning the expected increase in the workload for both the eCAs and the commenting Member States during the peer-review phase of Union authorisation applications, in the CAs

the experts dealing with active substance approval are the same assessing biocidal products. In principle, it is expected that the same members will attend the discussions for both active substances and Union authorisation applications, but the participation of different or additional experts will be considered on a case-by-case basis depending on the specialism discussed.

The WG members expressed concerns regarding the alignment of the evaluations of Union and national authorisation applications with mutual recognition related to the same active substance(s)/product type(s) combination(s), in case horizontal issues are identified with an impact on both cases. ECHA commented that a recurrent item on the agenda of the Coordination Group meetings concerns a concise summary of the issues identified for Union authorisation applications, which can be of relevance for similar national authorisation. The agenda item was for information only and aims at raising awareness of the discussions in the context of Union authorisation applications.

After the update by ECHA, the eCAs gave presentations on the applications for products containing iodine/PVP-iodine they are assessing to highlight the main issues they have encountered during the evaluation. These presentations have already been uploaded to confidential part of S-CIRCABC.

The EFF WG members are encouraged to provide ECHA with any further input on the document *"Discussions and issues concerning Union authorisation expected at Working Groups and Biocidal Product Committee meetings"* by contacting the FMB: BPC-WGs@echa.europa.eu. No deadline is set for this action, as input can be sent anytime, as soon as they are identified. ECHA will inform in due time the eCAs about the organisation of an early Working Group discussions on Union applications for products containing iodine/PVP-iodine during the WG-III-2017.

8.7 DE concerns on OECD Guidance Document for Hard Non-Porous Surfaces

DE presented a document detailing the deficiencies in OECD tests for evaluating the activity of microbicides used on hard surfaces. Of particular concern are that the ratio between the volume of test substance and the surface area of the disk carrier is very high, and that only one concentration of the test substance is tested.

CH explained that these deficiencies have been highlighted already earlier, and even though US EPA is seeking adoption of the test methods as OECD Guidelines, it might be foreseen that they will remain as guidance documents. DE encouraged the EFF WG members to share their view on this issue.

8.8 Other information & lessons learnt

ECHA informed about the status of the combined CAR-CLH report template. The final version of this template will be available on ECHA website possibly end of March 2017. The EFF WG members were informed that next meeting is planned to take place in Helsinki (31/05-1/06/2017). This will be confirmed by ECHA in the near future.
With reference to e-consultations initiated by the MSs ECHA presented short instructions as a recommendation on how to launch such consultation with reference to the distribution list, subject and deadlines. In addition it was proposed to include additional agenda point under AOB: *'Update on ongoing and recently finalised e-consultations'*. MSs, who initiated them will be invited to give a brief information during the meeting. The Chair informed that ECHA is placing all e-consultations on CIRCABC. E-consultations involving IND are placed in the non-confidential part and e-consultations only between MSs in confidential part of CIRCABC.

Minutes of Environment WG

WG-II-2017 (14-15 March 2017)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 18 participants present, of which eight were core members and ten flexible members. One representative from accredited stakeholder organisation was present for agenda item 7. Applicants were registered for their specific substance discussions.

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

2. Administrative issues

SECR gave a brief presentation on housekeeping and administrative issues. The WG members were informed that R4BP 3 should be used for communication (First Draft CARs); the "Submissions" folder in S-CIRCABC will not be available for this purpose after the process flow 19 (18 March 2017).

The SECR explained that the file naming in S-CIRCABC will be streamlined in the following manner: Folder/Space name – "Draft CAR" (including sub-spaces "Draft CAR_v1", "Draft CAR_v2" etc.) and the folder/space name "Final CAR" should include only last final version of the CAR – the change will be reflected in the Biocides Active Substances IG structure.

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 were declared.

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

The minutes were agreed without further changes. The minutes for imiprothrin and cholecalciferol will be agreed in a written procedure due to late comments.

6. Discussion of active substances

6.1 Cyphenothrin (eCA EL) – PT 18

Four points related to effect/hazard assessment and three points related to the exposure assessment were discussed. On point remained open and an ad hoc follow up was triggered. The ad hoc follow up will be initiated as soon as the conclusions of EFF WG-III-2017 are available.

Action: eCA to prepare the ad hoc follow up document/SECR to initiate ad hoc follow up (after EFF WG-III-2017).

6.2 Agreement on harmonised endpoints for pyrethroid metabolites (eCA UK and EL)

One point related to the harmonised list of endpoints for pyrethroid metabolites was discussed regarding the active substances imiprothrin and cyphenothrin. The Working Group members agreed on the evaluation of the eCAs. The eCAs can proceed with the preparation of the updated CARs.

6.3/6.4 MBO - 2, 6, 11, 12, 13 / HPT - PT 2, 6, 11, 13 (eCA AT)

Five points related to effect assessment and thirteen points related to exposure assessment were discussed. Two points remained open, for which two respective ad hoc follow up were triggered. For a third point the need for an ad hoc follow up will be decided based on the outcome of the ad hoc follow up for one of the open points mentioned.

Actions:

- eCA to prepare the documents for the ad hoc follow ups and SECR to initiate the ad hoc follow ups.
- SECR to reflect in the update of the TAB the conclusions noted for points 7, 11 and 14 of the discussion table.
- SECR to follow up with policy makers (first BPC) on the comparison of $PEC_{surface\ water}$ to drinking water limits; if needed an e-consultation of the ENV WG will be initiated.

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).

7.2 Data requirements for precursors of in situ generated active substances

1) Decision tree "Identification of precursors subject to risk assessment". On the basis of the feedback of the WG, SECR considered there were 3 main options to follow with the assessment of precursors (and by analogy any other constituents of the substance generated *in situ* other than AS ingredients):

1) Apply 0.1% trigger (i.e. the original decision tree as given in Figure 2 Identification of precursors subject to risk assessment of the document WGV2016_ENV_7-4_Precursors *in situ* generated AS)

2) Apply 5% trigger (i.e. 0.1 % is replaced with 5 % in the original decision tree as given in Figure 2 Identification of precursors subject to risk assessment of the document WGV2016_ENV_7-4_Precursors *in situ* generated AS)

3) Follow Guidance of SoC in full (Figures 2 and 3 in the WGV2016_ENV_7-4_Precursors *in situ* generated AS are not applicable)

Which of the options should be followed?

Conclusion: The WG agreed that a hazard assessment should be performed for all substances independent of any trigger value (based on the guidance provided in the guidance on SoC, i.e. based on minimum data like QSARS, literature or SDS). If SoCs are identified, for these a risk assessment should be performed according to the figure 3 of the draft document *WGV2016_ENV_7-4_Precursors in situ generated AS*. For all other substances (unreacted precursors and other constituents like reaction by products) a risk assessment according to figure 3 should only be performed if they occur above 5%. Figures 2 and 3 will be adjusted accordingly.

2) Exclusion and substitution criteria. Does WG agree that in addition to properties of the active substance generated *in situ* the properties of other constituents of the *in situ* generated

substance should be considered when concluding on whether the exclusion, substitution and Annex I listing criteria are met during the approval process of the active substance generated *in situ*?

Two WG members reacted to this question and were of the view all constituents of the *in situ* generated substance should be considered when concluding on whether the exclusion, substitution and Annex I listing criteria are met during the approval process of the active substance generated *in situ*. Safety of the system as a whole was used as an argument.

7.3 Outcome of the PT 18 Expert Group meeting (PT 18 - stable and manure applications) (ECHA)

The ENV WG re-confirmed the conclusions of the PT 18 EG, the detailed conclusions are provided in Appendix 2 below, agreed actions are provided in the following.

Actions:
SECR to include agreed items in the TAB.
PT 18 EG members to perform the agreed calculations before 14 April 2017.
DK to provide revised scenario for mink stables, **SECR** to send the scenario to the AHEE for confirmation.

7.4 Information on batches used in ecotoxicity testing (ECHA)

SECR presented the final version of the paper information on batches used in (eco) toxicity testing including the comments made at WG-I-2017.

Action: SECR to include the final version of the tables in the CAR template.

7.5 Harmonisation of PT 21 freshwater scenarios (NL)

The NL presented a plan and time schedule to agree on a harmonised scenario for the environmental risk assessment of antifouling products (PT21) for application on a) freshwater pleasure craft and b) freshwater commercial vessels by 31 July 2017. The following options were discussed for the foreseen scenarios.

1. Fresh water pleasure craft scenario:
- Option A – Approach comparable to saltwater marina method
- Option B – Selection of one freshwater marina used in MR

Action: MSs will collect data for option A. The deadline to provide the data to the NL is 12 April 2017.
Additionally MS should inform within a week after the WG meeting if the proposed deadline to provide information could be met. If the information will not be available then option B will be followed.

2. Freshwater commercial vessels:
- Option C- Development of scenarios based on data submitted
- Option D- Development of scenarios by NL

Action: MS will provide the available relevant information for the development of the scenario to the NL by 12 April 2017. NL will inform the WG on the progress of the development of the scenario.

7.6 Outcome of e-consultations initiated in Q4 2016/Q1 2017 (DK, UK, ECHA)

1.) Questions related to the existing scenarios for PT 4 (disinfection of food vessels and machinery disinfection) - DK

DK reported the following outcome of the e-consultation:

In order to back up the give amount of a biocidal active substance per year in the total plant, more information should be available to conclude on the quantity of substance used per plant (e.g. market survey or literature data).

Degradation should not be taken into account in the use phase, unless degradation can be documented based on monitoring studies in several facilities.

Degradation in the sewer system: a sewer residence time of 1 h, proposed as default value in the ESD for PT5, will be used for the calculation. The value of 1 hour is based upon an average distance of 4.5 km from the point of release to the STP and an estimated flow rate of 1.5 km in 20 minutes in the municipal canal sewer system.

Conclusion: No further action is needed since the e-consultation was substance specific and the proposed scenario including a full description will come back to the ENV WG when the substance is discussed at WG meeting level.

2.) Aircraft disinsection PT 18 - UK

UK reported the following outcome of the e-consultation:

Do MS agree that assessment looking only at airborne discharges is not sufficient to quantify ENV risks posed by use of these products?

For non-volatile actives, consideration of losses to the air compartment is not appropriate. In such cases, the major route to environment is most likely as a result of wet cleaning treated surfaces (including deposition onto passengers), where discharges are directed to local STP.

Do MS consider that 100 % of a.s. applied in aircraft could reach surfaces, either as a result of direct spray contact or deposition of low volatility actives? If so, then do MS consider the 3 potential emissions episodes reflect sensible and realistic opportunities for releases?

For non-volatile actives, consideration of losses to the air compartment is not appropriate. This approach was supported by the published paper (E. Berger-Preiß *et al*, 2006) supplied by one commenting MS, which concluded that >99% of an applied substance could be expected to deposit to surfaces 20 min after application of disinsection products.

Do MS broadly agree with the assumptions made in quantification of losses to local STP arising from daily (wet) cleaning of aircraft?

In the absence of other reliable data specific to national conditions, the assumptions regarding losses to STP from wet cleaning of toilets, galley areas of aircraft between flights could be accepted as realistic.

If detailed argument and evidence of typical working practices can be provided, would MS accept that negligible emissions can be expected for wet cleaning of internal surfaces provided that disposable cloths or disposable wet wipes are used? All contaminated material would then be disposed of safely via approved contractor.

Whilst it was agreed that emissions from disposable cloths would lead to negligible emissions to STP, detailed information on the cleaning processes, areas cleaned, working practises and steps taken to ensure that all cleaning cloths are disposed of safely (and not rinsed out) must be provided to demonstrate that negligible emissions / zero risk can be achieved.

Do MS broadly agree with the assumptions made in quantification of losses to local STP arising from routine deep (wet) cleaning of aircraft?

Whilst the commenting MS agreed with the general principle of the calculation to determine emissions to STP from deep cleaning of aircraft, one MS considered that certain airports could maintain more than 5 aircraft at a time and suggest that further investigation may be required.

If detailed argument and evidence of working practices can be provided, would MS accept that negligible emissions can be tolerated for wet cleaning of internal surfaces provided that disposable cloths or disposable wet wipes are used? For example, applicants have indicated that water is unlikely to be used in large quantities around wiring, avionics and electronic systems so solvent or glycol based wipes would be recommended. All contaminated material would then be disposed of safely via approved contractor.

Whilst it was agreed in general that emissions from disposable cloths would lead to negligible emissions to STP, the commenting MS indicated that detailed information on the cleaning processes, areas cleaned, working practises and steps taken to ensure that all cleaning cloths are disposed of safely (and not rinsed out) must be provided to demonstrate that negligible emissions / zero risk can be achieved.

Do MS broadly agree with the assumptions made in quantification of losses to local STP arising from passengers? Can we assume that laundering / bathing of 30 people per STP will occur on the same day?

The commenting MS considered that an assumption, that 30 passengers per STP may have been contaminated by disinsection products and could bathe / launder on the same day, is realistic.

Do MS consider that further refinements or mitigations are possible?

FR indicated that they would not be in favour of refinements to the proposed scenario without evidence and justification. DE indicated that work undertaken by national authorities showed that if disinsection product is applied 20 min before passengers board aircraft, then negligible contamination can be expected.

Conclusion: It was agreed that no further action is needed for the time being. UK will follow up the open points as far as possible in the frame of an ongoing product authorisation and if needed bring back the item to the ENV WG.

3.) Simplification of exposure assessment (all PTs) - ECHA

SECR provided information on the status of the consultation and noted that the item will be discussed at WG-III-2017.

In addition SECR reported that a request on the collection of tonnage data (related to the recommendation on Fpen) was send to the CA meeting. SECR further noted that if the CA meeting disagrees to start collection tonnage data, any further work on an alternative solution will be stopped and only the agreements taken so far will be summarised in the recommendation.

SECR further informed on the e-consultation of the BPC on environment related items identified at previous WG meetings.

7.7 New developments on mixture toxicity (DE)

DE made a presentation of the “New developments on mixture toxicity” which cover the preliminary results from a R&D project on the mixture toxicity assessment of biocidal products. In this work, real products were tested on different aquatic species and then a comparison was made between the results of the aquatic tests and the results estimated by the current methodology for the assessment of mixtures explained in the “Transitional Guidance on mixture toxicity assessment for biocidal products for the environment”. After the presentation, several members and SECR made some comments and questions on the findings presented by DE. In general, the work was perceived as a preliminary work with limited number of products tested in order to reach conclusions on whether the current methodology underestimates the risk of biocidal products. The WG agreed to follow up on the item when new results are available together with experience gained with product authorisation.

8. AOB

8.1 Update on Union Authorisation

An update on Union authorisation was given by the SECR and evaluating MSCAs to present an overview of the current status of the applications submitted so far and an outline of the ongoing activities. SECR presented a proposal about the planning for the discussion at the Working Group and BPC meetings of the first applications expected to enter the peer-review phase in 2017.

The document "Discussions and issues concerning Union authorisation expected at Working Groups and Biocidal Product Committee meetings" aims at highlighting potential issues that might be raised during the discussions at the Working Group and BPC meetings. It is considered as a living document that can be updated as experience is gained in the peer-review of Union authorisation applications. The WG members may provide any further input on the document by contacting the functional mailbox BPC-WGs@echa.europa.eu. The document is available to MSCAs in S-CIRCABC:

- Path: /CircaBC/echa/BPC-WG/Library/Confidential/06. Common issues/Union authorisation
- Browse url: https://webgate.ec.europa.eu/echa-scircabc/w/browse/6e6b8ac4-2e9b-43d3-b082-56da5ebe50ad

After the update by SECR, the evaluating competent authorities gave a presentation on the applications they are assessing to highlight the main issues they have encountered during the evaluation.

NL informed the WG that the C&L assessment required a re-arrangement of the family structure. In addition, NL explained how they applied the ambient background concentration as PEC, resulting in acceptable PEC/PNEC ratios > 1. Similarly, UK reported ambient iodine background values above the PEC value. UK expressed the wish to cover the re-occurring issue of the teat size in the early WG discussions. ECHA informed the WG on current in-house discussions as to whether C&L was within the remit of the WG.

Actions:

- WG members to provide SECR with any further input on the document "Discussions and issues concerning Union authorisation expected at Working Groups and Biocidal Product Committee meetings" by contacting the functional mailbox BPC-WGs@echa.europa.eu. No deadline is set for this action, as input can be sent anytime, as soon as they are identified.
- SECR to inform in due time the evaluating competent authorities about the organisation of an early Working Group discussion on their applications during the WG-III-2017.
- SECR to upload the presentations of the evaluating competent authorities to S-CIRCABC.

8.1 Other information & lessons learned

The following information were provided:

The WG minutes currently indicate specific members, noted by the MS name and are not anonymised. The WG members were asked if they further support the non-anonymised version, which they did.

Action: SECR to check agreement with WG members not present at the meeting.

Concerning the timing of agendas it was noted that the provisional draft agenda is uploaded to the ECHA webpage (https://echa.europa.eu/documents/10162/22866449/wg-ii-2017_agenda_en.pdf/c1805e45-04fe-8339-db7e-6e41c1e0184c) at least four weeks before the WG meeting (in parallel to the meeting invitations). The revised agenda is uploaded to the ECHA webpage as well as to S-CIRCABC at least ten days before the meeting (in parallel to the discussion table upload). If items change still added afterwards, an updated agenda is uploaded to S-CIRCABC and/or send by email.

SECR further reminded on the Newsgroup (https://webgate.ec.europa.eu/echa-scircabc/w/browse/94cce2dc-6a4b-4d0c-a1d6-d9c99f83454c) on open emission scenario related items (per PT) and asked MS if they add any item to include also a prioritisation of this item.

SECR provided an update on the ongoing revision of Vol. IV Part B and presented the new guidance structure on the ECHA webpage.

An update on the planning of the ESD spreadsheet preparation as well as on the combined CAR/CLH template was provided.

It was further noted that in case the PEC is higher than MAC EQS, argumentation to be provided in the CAR - item will be added to the extended accordance check template.

The following lessons learned were presented:

MS were reminded to keep the timelines, specifically for trilateral discussions and for providing the updated RCOM table and clearly indicate open/closed items.

It was further noted that bilaterally changed PNEC value in the RCOM should always be confirmed by ENV WG and the related RCOM item should therefore be classified as “open”.

Additional items raised by WG members:

It was noted that it would helpful to add in the subject line of messages send via S-CIRCABC the relevant WG which is concerned by the message.

Appendices:

Appendix 1:

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

Note:

- Issues unchanged since WG-I-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**	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. **The PT 21 PA manual was endorsed at WG-I-2017, some items were forwarded to the 70th CA meeting.** **NL will present the status for fresh water marinas at WG-II-2017.**
1.2	Leaching to groundwater from paint, coatings and plaster (**NL**)	The document was discussed at WG-II-2015. NL agreed to make some clarifications in the document for better readability. The document was distributed for commenting after WG-II-2015, no comments have been received (commenting period ended on 8/5/2015). DE commented directly to NL during the physical meeting. **The document will be updated and NL will explain the method in more detail**.
1.3	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. **The document was endorsed at WG-I-2017 and will be included in the TAB 1.3.**
1.4	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[6] 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.

[6] **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
1.5	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)**.
1.6	1st revision of Vol. IV Part B (active substance) + new biocidal product part including SoC) (**ECHA**)	1st revision: definition of subjects for first revision and assignment of volunteers taking over the subjects were agreed at WG-I-2016, revised text parts have been provided by 15 June 2016. After discussion of some items at WG-IV-2016. The PEG consultation was initiated in December 2016. **Discussion of the revised text will take place in the frame of the PEG. PEG meeting takes place on 16 March 2017.**
1.7	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 to initiate e-consultation after the WG meeting.
1.8	TAB (**ECHA**): Technical Agreements on Biocides	The second revision of the TAB was finalised, containing now also APCP items (TOX and ENV unchanged). The next revision resulting in version 1.3 contains revised TOX and ENV entries and will be distributed in March 2017 for a six week commenting period.
1.9	ESD for PT 6 (**DE**)	DE has revised the ESD following comments received. **The ESD was endorsed at WG-I-2017, DE to provide the final version to be placed on the ESD webpage.**
1.10	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.
1.11	Guidance on mixture toxicity (**DE**)	Will be presented at WG-II-2017 for information and to a certain extend discussed in the frame of the PEG meeting on the revised Vol. IV Part B (PEG meeting).

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*	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 **and was forwarded to the 70th CA Meeting. Revised recommendation to be prepared by SECR after the CA meeting, endorsement of revised**

No.	Title (current leader)	Status
	(pulp and paper processing fluids)	**recommendation by ENV WG scheduled for WG-III-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 were endorsed at WG-I-2017, conclusions to be added in the TAB 1.3.**~~
~~2.3~~	~~PT 18: Development of equations to take into account degradation in manure~~ ~~⇨ *WG-V-2015 – item 7.2b*~~	~~NL volunteered to take over this point.~~ ~~**Discussion at AHEE-1, endorsement at WG-V-2016. Several members will provide further comments on minor issues directly to NL. Document will be included in TAB 1.3.**~~
2.4	Clarification on DT50 values according to the FOCUS guidance to be used for modelling purpose and as trigger value (for higher tier studies/PBT assessment) ⇨ *WG-I-2016 – item 6.3b*	**DE / UK** volunteered to take over the item (update of PBT guidance to be taken into account). Timing to be defined.
2.5	Proposal on exposure assessment of metabolites in the terrestrial compartment ⇨ *WG-II-2016 – item 6.4*	DE will prepare a proposal for discussion. Discussion at AHEE-1 and WG-V-2016. **An e-consultation was initiated after the WG meeting to close points 3 to 7. If the results of the consultation is unambiguous, the document will be endorsed in a written procedure. If not, the item will be re-discussed at WG-III-2017.**
~~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.~~ ~~**Item was endorsed at WG-I-2017, conclusions to be added in the TAB 1.3**~~
2.7	PT 3: Scenario for disinfection in aquaculture ⇨ *Disinfection project/EMA visit*	ECHA contracted out the preparation of a first proposal. **First discussion took place at WG-I-2017, comments received during the commenting period to be added. Revised version will be provided for discussion agreement in Q3 2017.**
2.8	PT 21: How to use data on background concentrations in the env. risk assessment ⇒ *WG-IV-2015 – item 6.3* *(reference below the DTs to the respective RCOM table entries)*	FR volunteered to take over the item. Timing to be defined.
2.9	PT 11: Which fraction should be used to calculate the PEC in soil following deposition from air? ⇨ *WG-IV-2016 – item 6.3*	NL volunteered to take over the item. Timing to be defined.
OPEN ITEMS (priority indicated in colours: high = red, yellow = medium, green = low; prioritisation based on the time lines provided in Annex III of the RPR)		
2.10	PT 18: How to derive values for the cleaning efficiency FCE (=> Release and exposure estimation of the biocidal product during cleaning step) ⇒ *WG-III-2015 – item 6.4*	AHEE member to take over item to be assigned.

No.	Title (current leader)	Status
2.11	PT 8: Use of a standard transfer factor (38 or 40) for transferring an application rate per volume to an application rate per surface (leaching rate assuming 100% leaching) or use of a specific transfer factor based on the dimensions of wooden commodity per scenario (of OECD ESD PT 8). ⇒ *WG-IV-2015 – item 6.3*	AHEE member to take over item to be assigned.
2.12	PT 6: Development of an emission scenario for the preservation of unrefined fuels ⇒ *WG-V-2015 – item 7.3*	AHEE member to take over item to be assigned
2.13	Development of RTU/small scale application scenario for PT 18 (household and professional use) ⇒ *WG-II-2016 – item 6.2*	AHEE member to take over item to be assigned.
2.14	Development of a proposal on how to use Fsim in an aggregated exposure assessment for PT 18 ⇒ *WG-II-2016 – item 6.2*	AHEE member to take over item to be assigned.
2.15	Refinement options for PT 11 once through and large recirculating systems ⇒ *WG-II-2016 – item 6.8/6.9*	AHEE member to take over item to be assigned – document form industry awaited.
2.16	PT 21: AHEE consultation - consideration of the PT8 ESD for accumulation and degradation processes (equation 3.11), and the emission pattern for soil exposure (batch-wise vs. continuous release). ⇨ *WG-III-2016 – item 6.4 (AHF)*	SECR to initiate.
2.17	PT 8: Proposal for emission scenarios on how to assess short term antisapstain treatments *WG-III-2016 – item 6.7/BPC-17*	AHEE member to take over item to be assigned.
2.18	PT 7: Revision of the ESD (inclusion of the formulation step, alignment of equations with A/B tables) ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.19	PT 9: Definition/revision of fixation factors for PT 9 – leather applications ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.

No.	Title (current leader)	Status
~~2.20~~	~~PT 18: Area of animal housing to be considered for applications in PT 18~~ ~~⇨ *WG-IV-2016 – item 7.3*~~	~~Discussed in the frame of the PT 18 EG meeting.~~
~~2.21~~	~~PT 18: Land application interval and manure storage period in PT 18~~ ~~⇨ *WG-IV-2016 – item 7.3*~~	~~Discussed in the frame of the PT 18 EG meeting.~~
2.22	PT 10: Removal processes ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.23	PT 9: Concentration in soil in PT 9 rubber-roof membrane scenario ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.24	Focus SWASH: Use of the model for calculation of PEC in sediment (PT 3, run-off from soil) ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.25	PT 4: Is splitting up the release from on-site/off-site STP in the case of large breweries relevant and is the proposed percentage (on-site = 33% / off-site = 67%) realistic? ⇨ *WG-V-2016 – item 6.1*	NL volunteered to take over the item.
2.26	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*	
2.27	Development of guidance for bees and non-target arthropods ⇨ *CG (2017)*	

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

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

No.	Title (current leader)	Status
~~3.1~~	~~PT 18: Consultation on ESD PT 18 (household + professional uses) - bait box scenarios (**NL**)~~	~~Questions raised by NL in the frame of MR, consultation initiated on 15 September 2016. Comments have been received from DE and FR.~~ ~~**Questions were included to item 7.3 of WG-V-2016, will be partly taken up by DE in the revision of the ESD for PT 14 (tbc).**~~

No.	Title (current leader)	Status
~~3.2~~	~~PT 18: Clarification of areas to be considered for wet cleaning (**UK**)~~	~~Deadline for commenting was 21 October 2016, comments have been received from CH, FR, DE, PL, DK.~~ ~~**UK will report outcome at WG-I-2017**~~
3.3	PT 4: New emission scenarios for DBNPA (**DK**)	Deadline for commenting was 4 November 2016, comments have been provided by NL, DE, FR, UK. **DK will report outcome at WG-II-2017**
~~3.4~~	~~PT 18: Market data for refinement of the exposure assessment (**DE**)~~	~~Deadline for commenting is 30 November 2016.~~ ~~**DE will report outcome at WG-I-2017**~~
3.5	PT 18: Aircraft disinsection (**UK**)	Deadline for commenting is 31 January 2017. **UK will report outcome at WG-II-2017/WG-III-2017**
3.6	Simplification of exposure assessment (all PTs); initiated post WG-V-2016, relevant for PA authorisation/AS approval (**SECR**)	Deadline for commenting is 3 February 2017. **Item will be scheduled for discussion at WG-III-2017.**

Appendix 2: Item 7.3 - PT 18 Expert Group Meeting conclusions agreed by the ENV WG

Introduction:

In the following table "**Conclusions PT 18 Expert Group Meeting**", the items for discussion at the PT 18 EG meeting as well as the conclusions and actions agreed at the expert meeting confirmed by the ENV WG at WG-II-2017 are provided. The items for discussion had been either identified at previous WG meetings or had been provided in the dedicated Newsgroup set up after WG-V-2016.

Discussion table - conclusions PT 18 Expert Group Meeting			Meeting dates: 14-15 March 2017	
a) No.	**b) Issue and background Ref. in RCOM**	**c) PT 18 EG - open/closed point and conclusions**	**d) PT 18 EG - action points**	**WG-II-2017 - conclusion**
Items related to the ESD on stable/manure applications (PT 18 EG meeting)				
1.	WG-IV-2016 – Item 7.2b: Values for Focus PEARL simulations DE would like to discuss which value should be used if calculations with Focus PEARL have to be performed (especially with regard to the different a.s. contents in each 53 d-interval) in cases where degradation processes in manure are considered. NL indicates that in the situation without degradation in manure, there would have been four PEARL application dates with four equal active concentrations in manure; now there will be four dates, but with four unequal active concentrations. NL further notes that although there will not be a large change, it has not been agreed yet on how to choose the four application dates in PEARL. *SECR note: The item on the application dates was discussed separately at WG V (WGV2016_ENV_7-2a) in which the WG and agreed to follow option 2.* *NL updated the draft Recom on degradation in manure in line*	**Point closed.** It was agreed for the time being for simplification reasons, until further calculation tools are available, to use of the same maximum value four times as input parameter in PEARL (instead of using four different values taking into account degradation); provided that this does not result in an exceedance of the groundwater limit value.	--	The WG confirmed the conclusion of the PT 18 EG.

Discussion table - conclusions PT 18 Expert Group Meeting				Meeting dates: 14-15 March 2017
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	with this conclusion for WG V. This document was then also agreed. Therefore the item is only provided for information. **To be discussed:** Which value should be used if calculations with Focus PEARL have to be performed?			
2.	<u>WG-IV-2016 – Item 7.2b: Prescribed number of applications falling outside the grassland period</u> DE notes that if the applicant prescribes a number of applications per year, it can happen that some of the biocidal applications are not covered by the grassland risk assessment at the moment. In DE opinion the remaining number of prescribed applications has to be included in the 4*53 d-intervals and questions how to deal with such cases. Example: 9 applications in a 28 d interval → in total 224 d (0,28,56,84,…, 224) 212/28=7,6 → 8 Applications → one application is not considered. NL reminds that the starting point is the ESD where Tbioc-int determines the number of biocide applications. With Tbioc-int = 28d and 212d of storage, 8 applications are possible but not 9. In case one wishes to have 9 applications with 212d of storage, Tbioc-int must be shortened. Furthermore NL adds that there will be differences in outcome, but it should always be remembered that if one extends the manure storage period to cover 'an extra application', there is	**Point open.** A follow up was concluded: test calculations will be prepared by DE, FR, UK, SECR to compare the current grassland approach (manure application interval of 53 days x 4 times) with a new approach, where there is no fixed number of manure storage intervals (number of intervals determined by the maximum number/prescribed number of applications of biocide to manure, and the prescribed use interval compared in relation to the manure amount produced during that time). The difference in the outcome will be assessed and then further followed up.	**Action:** DE, FR, UK, SECR	**Open**: The item needs to be followed further up by the PT 18 EG. Outcome of the calculations to be provided to NL/SECR **by 14. April 2017**. PT 18 EG to prepare a proposal following the calculations, to be confirmed by the WG.

Discussion table - conclusions PT 18 Expert Group Meeting				Meeting dates: 14-15 March 2017
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	also more manure produced, so in the end the resulting concentration change is not dramatically higher. After further bilateral discussion DE-NL propose to apply one of the following pragmatic solutions: 1) evenly distribute the extra applications over 4 storage periods or 2) shorten Tbioc-int. **To be discussed:** When the prescribed number of applications fall outside the grassland period can one of the following approaches be used and if so, which one: 1) evenly distribute the extra applications over four storage periods, or 2) shorten Tbioc-int.	Provided that the new approach is applicable, the next step would be to assess if the new approach can take into account degradation in soil.		
3.	<u>Area of the animal housing to be considered for the application in PT 18 (DE, UK, FR, 2nd batch, 1st round Excel sheet preparation)</u> The areas considered in the Excel sheet were: For larvicides: slatted area+other areas+manure area inside (areas from Table 5.3, ESD PT18 for stables) For insecticides: Total housing area (i.e. floor +wall and roof areas) (from Table 5.2) + Slatted areas and other areas (from Table 5.3) The commenting Members question the use of the areas above as seen as worst case situation. DE supports for spraying, foaming and fogging that all surfaces should be considered in PT18. However, considers for all other types of application in PT18 (sprinkling, smearing, bait) that it is still unclear if the	**Point closed.** The areas to be treated should be provided by the applicant. It was concluded that the Excel sheet will provide for surface and volume applications only the floor areas and housing volumes, respectively by default (according to Table 5.2 of the ESD) in case no information is provided. However, these should be overwritten by the areas provided by the applicant if available (e.g. only floor, 2 m	--	The WG confirmed the conclusions of the PT 18 EG.

Discussion table - conclusions PT 18 Expert Group Meeting				Meeting dates: 14-15 March 2017
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	total housing area should be taken into account. UK suggests that as the application is entered per floor area this value could be the default. FR questions whether it is possible to have the possibility to choose between different surfaces (floor, walls and roof, …). **To be discussed:** Which area should be used for the calculations for larvicides and for insecticides, for each different way of application (Spraying, Aerosol and fogging, Smearing, Sprinkling, Bait, Sprinkling and bait).	high band around the wall, etc.). A note will be added to the excel sheet, explaining the need to overwrite. The use prescription to be provided by the applicant should be very specific and provide all the areas to be treated.		
4.	<u>DE Item 1: Short intermediate discussion break at WG IV/2016 (ECHA, FR, NL, DE) on item manure application on arable land: Understanding of land application interval for arable land Tar2-int, manure storage time for arable land Tmanure-intar and time period of biocide application in stables Tbioc_int.</u> The repeated discussion on the realistic interpretation of these parameters was again opened by ECHA as this item is essentially for drafting the Excel-Sheets for PEC/PIEC calculations according to both OECD ESD PT18 No. 14 (2006) and Addendum (November 2015). DE would propose a more substantial amendment to consider only one period between 2 biocide treatments for PEC calculations. This period between two subsequent prescribed biocide treatments in stables is usually indicated by the applicant. Moreover, one of our main concern is that in case of an intended use of biocides in animal housings beyond the period of 212 days these biocide applications are excluded from emission	**Point closed.** **1. Arable land** The proposal of DE for arable land was accepted: Tar-int=Tbioc-int. It was noted that this scenario is the ESD scenario for arable land, as it is implemented in EUSES. It was also agreed that the values for Tbioc-int and Napp-prescr should be the values provided by the applicant, not the default values in the ESD. It was further agreed that this approach should be used for the arable land scenario in the addendum and in the ESD as	**Action**: DE will prepare a draft text for the TAB and cross-check with NL. UK will provide a draft text on the released to the STP (based on the CAR of azamethiphos). The draft TAB entry will presented at the WG-II-2017 for approval. Tier 1 and 2 are still to be confirmed based on examples:	Ad 1: The WG confirmed the conclusion of the PT 18 EG, however it is noted that the approach is only applicable if degradation in manure is not taken into account. Ad 2: **Open**. To be followed up by the PT 18 EG, calculations to be provided **by 14. April 2017**.

a) No.	b) Issue and background Ref. in RCOM	c) PT 18 EG - open/closed point and conclusions	d) PT 18 EG - action points	WG-II-2017 - conclusion
	estimation and can lead to an underestimation of PIEC and PEC values. According to ESD PT18 No. 14 the PECsoil (arable land) is calculated by $PIECar\_N_{i1\_i2\_i3\_i4} := \frac{Qai\_manure_{ar} \cdot Q_{N\_arable\_lan}}{Qnitrog\_arable_{i1\_i4} \cdot Nlapps_{ar} \cdot DEPTH_{arable\_}}$, where for the amount of active ingredient in relevant stream after the maximum number of relevant biocide applications (Qai_manurear) as well as for the amount of Nitrogen produced during the relevant period for the specific (sub)category of animal/housing i1 (Qnitrog_arablei1_i4) the same time period should be respected in connection with the number of biocide applications in one manure storage period. Thus, the same time periods are included in numerator and denominator of above mentioned equation. As an example: Napp_manurear will be equal to 1. The value of Qai_manurear is then calculated from only one biocide application and the value of Qnitrog_arablei1_i4 is calculated by the number of animals in housing, the amount of Nitrogen produced by specific animal per day and the number of days between 2 biocide applications (Tbioc_int). In our opinion, the proposal would implement the following advantages: – realistic worst case calculation for PIEC/PECsoil in arable land – no further discussions on fly seasons to be considered, on season for insecticide applications and on manure storage periods and number of biocide applications during these	a realistic worst case scenario. **2. Grassland** It was re-confirmed that for the number of applications of biocide during a storage period rounding should thake place to the first decimal. The approach as provided in the addendum to the OECD ESD (AHEE recommendation) should be used without further changes. In addition a tiered approach was proposed: Step 1 (screening): Scenario for **agriculturual land** = scenario for arable land with a soil depth of 5 cm Step 2: **Arable land** (scenario as proposed above) with a soil depth of 20 cm AND **Grassland** standard scenario including a soil depth of 5 cm. Approach still to be confirmed (see action in column e) The proposal after agreement by the ENV WG should be	DE, FR, UK, ECHA will run the calculations for 1-2 substances each to see whether the grassland scenario (Tier 2) can be worst case compared to agricultural land scenario (Tier 1).	

a) No.	b) Issue and background Ref. in RCOM	c) PT 18 EG - open/closed point and conclusions	d) PT 18 EG - action points	WG-II-2017 - conclusion
	periods – simplifying the Excel-Sheets PT18 (insecticides used in animal housings) for PEC-calculation provided by ECHA – simple transfer of calculation routines from OECD ESD PT18 No. 14 (2006) as well as from Addendum to OECD ESD PT18 No. 14 to the comparable situation in ESD PT3, where the consideration of specific seasons for biocide application will be obsolete and the whole year should be considered for disinfectant events and applications without regarding summer/winter season. We could present a more elaborated discussion paper/ppt of this proposal at the PT 18 EG meeting. However, as we are not convinced about the possible consent/support to discuss this proposal by the other experts/members of the meeting we would like to wait for responses before taking the next step. So, please write an e-mail until 10.01.2017 and indicate if you are interested in such a discussion. **To be discussed:** How should the parameters be interpreted: land application interval for arable land Tar2-int, manure storage time for arable land Tmanure-intar and time period of biocide application in stables Tbioc_int?	included in the TAB.		
	Background During the commenting of the first draft of the excel sheet for PT18 we received the following comments: DE agrees that both Tar2-int (land application interval for arable land) and Tmanure-intar2 (manure storage time arable land), 365 d respectively 212 d, should be considered, in accordance with the Addendum to OECD Series on ESD, No. 14, ENV/JM/MONO(2006)4, WG Env V, Nov 26, 2015.			

Discussion table - conclusions PT 18 Expert Group Meeting				Meeting dates: 14-15 March 2017
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	FR does not agree with the calculation of Qnitrog-arab that is calculated based on Tar2-int of 365 days and that should be calculated with Tmanure-intar2 of 212 which is the storage period and not the time between two manure applications on land. The UK questions the use of the Tarint value of 365 days.			
5.	<u>DE Item 2: Scenario degradation in manure for arable land</u> DE notes that there should be only one scenario with Tmanure_int (manure storage period) of 212d. NL supports using the new scenario, because the current ESD scenario is interpreted differently due to unclear description of parameters and units in Table 5.8 (ESD p. 45). **To be discussed:** Does the WG agree to replace the arable land scenario in the ESD by the arable land scenario in the document Addendum to OECD ESD no. 14 (ENV/JM/MONO(2006)4)? Excel sheets and EUSES have to be adapted accordingly.	This item is covered by the conclusions for point 4.	--	
	Background This issue had been included in the discussion table for item 7.2b of the WG-IV-2016, and had been concluded that the issue is linked to a potential revision of the ESD and would be further discussed in the frame of the clarification on open items in the ESD. For further details see <u>"WGIV2016_ENV_general_final_minutes"</u>, the minutes of the meeting embedded under point 8 below.			
6.	<u>DE Item 3: Environmental exposure pathway – Poultry housings: Releases of a.s. to waste water which is directed to local STP or added to dry/liquid waste (manure/slurry) and applied to agricultural land</u> General awareness to the subject that for some poultry housings two calculations have to be performed: One for the case that these poultry housings (i1=8, 11, 12, 16-18) are connected to the local sewer system with subsequent release to	*Item provided only for information/discussion, it will be forwarded to the ENV WG to decide on the proposal.* Concerning the distribution to the different recipients (STP, manure/slurry), reference was	*ENV WG to follow up.* **Action**: SECR to adapt the ESD Excel sheet accordingly for 5 animal categories: 8, 11, 12, 16-18.	The WG agreed that a calculation routine should be added to the excel sheet to cover the situations where the housing is not connected to the sewage system (i.e.

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	a STP. And one for the case that waste water and manure/slurry are collected in one storage tank and are spread together to agricultural soil. **To be discussed:** DE proposes that a calculation routine is added to the excel sheet for PT18 animal housings, to cover the situation where the housing is not connected to the sewage system, and therefore the wastewater remains on site and is stored with the slurry prior to mixing with dry waste (manure) for application to agricultural land (soil). Thus, a.s. residues in waste water fractions should be added to a.s. residues in slurry/manure. Do the WG members agree?	made to the wording for azametiphos to be provided by UK (which will be added to the TAB). The ESD Excel sheet will be adjusted accordingly.		residues in waste water fractions should be added to the residues in slurry/manure).
	Background: With regard to ESD No. 14/PT 18 (p. 19, figure 4.1 and p. 40/41 Table 5.4) the biocide application in poultry housings which are not connected to the local drainage systems can lead to additional a.s. fractions in manure/slurry.			

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	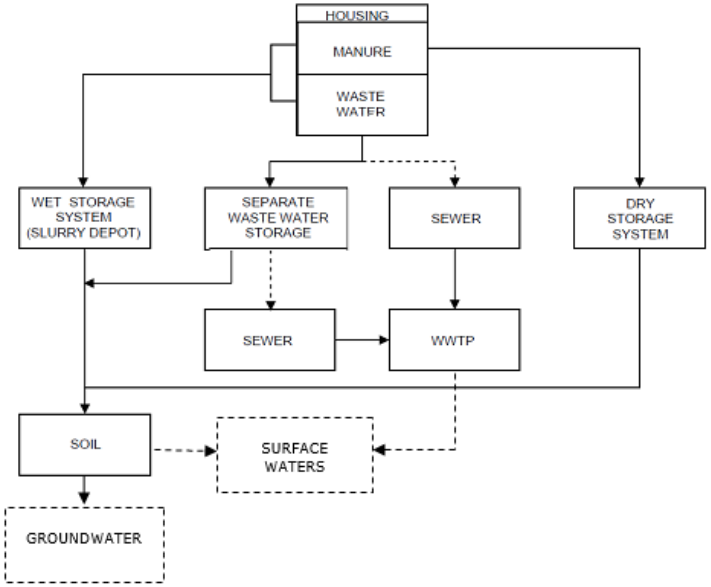 Where the housing is not connected to sewage systems, the wastewater (only relevant for poultry housings) remains on site and will be stored with the slurry prior to mixing with dry waste (manure) for application to agricultural land (soil). Thus, a.s. residues in waste water fractions should be added to a.s. residues in slurry/manure. We would refer to the CARs of Imidacloprid, Cyfluthrin (DE) and Azamethiphos (UK) where these considerations are well explained and the calculation steps are considered for realistic PECsoil assessment. In particularly, the different applicable scenarios 1-5 are well described by simple, comprehensible means in CAR for Azamethiphos (page 183-184). DE would support the implementation of the calculation routine in the Excel-Sheet for PT18 animal housings.			
7.	DE Item 5: Influence of the rounding procedure in the addendum	The items is covered by the conclusions of point 2 (further discussed also within point 4).	--	

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	At WebEx-meeting in September, DE agreed to support NL and check the influence of the rounding procedure. For the addendum "Addition of calculation routines to incorporate degradation in manure" it was agreed, that the real number of applications within a storage period has to be used. On the other hand in the addendum for ESD PT 18 agreed at ENV WG V 2015, rounding to one digit for calculations concerning manure applications to soil was adopted. Some MS (NL, FR and ECHA) voted to maintain this approach. DE compared the two approaches and the influence of the rounding procedure and found that the deviation of the two results was within 11.26%. **To be discussed:** Given the deviation found between the two approaches, and the discussion that took place at the WGIV2016, how do the WG members suggest to conclude on this point?			
	Background: From the "WGIV2016_ENV_general_final_minutes": Point 7.2b – 8 Number of application intervals within one storage period – terminology **Conclusion of the breakout group:** Point open. There was an agreement that for degradation in manure the absolute number should be used. However, before finally concluding, it needs to be checked what would be the implication on the first recommendation prepare by NL (Addendum to the OECD ESD provided in the TAB v1.1, entry ENV 89). **Agreed actions by the breakout group: NL** to follow up implications on the first recommendation.			

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	See Appendix 2 of the "WGIV2016_ENV_general_final_minutes" (embedded) for details on the discussion on this point.  WGIV2016_ENV_general_final minutes.d			
8.	DK – Item 2: Suggested emission scenario for flee products in mink stables. The DK CA has received applications for control of flees in mink stables. As the ESD for PT18 does not include a scenario for mink stables, the DK CA suggests an emission scenario considering conditions in the Nordic countries (see attached word document).  emission from mink stables	*Item provided only for information/discussion, it will be forwarded to the AHEE for confirmation in an e-consultation (ENV WG to confirm).* It was concluded that a written procedure with the AHEE should be initiated to confirm the proposed scenario.	**Action**: SECR	The WG agreed that the scenario should be send to the AHEE for confirmation. DK to provide an updated version to SECR.
9.	NL Item 4. Emission from washing of coveralls after PT18 stable applications Coveralls worn during treatment of stables can be washed - in line with ESD OECD nr. 18 for household and professional uses. Therefore emission to the STP / IBA (Individual Wastewater Treatment System) and the receiving aquatic environment from this event may occur. ESD OECD nr. 14, however does not include this scenario. Do the WG members agree to add the calculation of the emissions from the applicator to the scenarios?	*Item provided only for information/discussion, it will be forwarded to the ENV WG to be agreed if it is a relevant AHEE item.* The PT 18 EG was not in favour to add an additional scenario for the following reasons: - Coveralls may be disposable in some of the	*ENV WG to follow up.*	The WG confirmed that the emission form washing of coverall after PT 18 stable applications does not need to be assessed and no additional scenario is needed.

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		farms. - Release may be covered by other releases from the stable to the STP. - It is a single events after insecticide application. - Coveralls are potentially not washed at the same day when the stable is treated (no aggregated exposure). - Potentially covered already in the fraction released provided in the ESD. - Mixing and loading step is not included in the ESD for PT 14.		
10.	<u>NL Item 6. Waste water stream in stables</u> Cleaning of stables will result in an emission of PT18 products to the manure deposit with waste water, but waste water may also be released to the sewer (connected to the STP, releasing to surface water). In the Netherlands, both options are (legally) allowed and are likely to occur in practice. However, the ESD does not consider emission to waste water as a relevant route for several animal categories, which seems not to correspond with the current Dutch situation. We propose to perform a focused enquiry amongst MS to enquire the practice and legal contraints in their country. Based upon the outcome it may be decided to add the emission route of waste water to the STP (following cleaning of stables).	*Item provided only for information/discussion, it will be forwarded to the ENV WG to decide on the follow up.* FR/FI/DE/UK noted that a release to the waste water stream is not allowed per se. There can be however special agreements for single farms.	*ENV WG to follow up.*	The WG agreed that this exposure pathway does not need to be assessed. Only NL noted at the WG meeting that it is a relevant pathway.

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	Do the WG members agree to the NL proposal above?			
11.	<u>SE Item 1: Additional environmental exposure scenario – Treatment of animal transport vehicles</u> SE would like to propose that <u>treatment of animal transport vehicles are considered for PT18</u>. This could be an addition to ESD OECD no 14 (Emission scenario document for insecticides for Stables and Manure Storage Systems). This use was discussed during product authorisation and mutual recognition of K-Othrine SC 7.5. NL suggested that animal transport vehicles are often cleaned in a manner such that the wastewater is led to a drain and thus leads to exposure of STP and so on. Animal transport vehicle scenario is included in PT3. Could this scenario be used? Does it need to be altered to fit the PT18 use patterns? Do the WG members agree to the SE proposal above?	*Item provided only for information/discussion, it will be forwarded to the ENV WG to be agreed if it is a relevant AHEE item.* The PT 18 EG sent back the question back to SE: is this really a relevant use since animals are usually not kept in vehicles for longer periods. Means use could be relevant for PT 3 but rather not for PT 18. In principle it would be acceptable to use the scenario for PT 3 (applicability of default values to be verified) for a product for this specific use, however there is no need to have it as a general scenario in PT 18 (stable/manure application).	*ENV WG to follow up.* **Action:** SE to provide feedback at WG-II-2017	The WG agreed that for the time being there is no need to develop a corresponding scenario. If there will be in the future a related application (AS or product) the item will be further followed up.

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12.	<u>SE Item 3: Simplification of mutual recognition process: OK for Ref-MS to only include worst-case animal groups for stables/manure storage scenarios?</u> During product evaluation of K-Othrine SC 7.5, use in stables was evaluated. Ref-MS evaluated all kinds of animals that are included in the ESD. In the PAR, however, only the worst case animal groups were shown (livestock and poultry). This was questioned by cMS. All animal groups should be evaluated for uses in animal housing. Is it necessary to show all results from all animal groups in the PAR? (even if the risk is acceptable for all animal groups?). **To be discussed:** Do the WG members agree to the SE proposal above?	*Item provided only for information/discussion, it will be forwarded to the ENV WG to decide on the proposal.* The PT 18 EG agreed that all initial PIECs should be added in an Appendix of the PAR to show the derivation of the worst case. It is then sufficient to perform subsequent calculations only with the identified worst case scenarios (only these are then to be described in the PAR).	*ENV WG to follow up.*	The WG agreed to the procedure proposed by the PT 18 EG. In a first step it is sufficient to only provide the (single) worst case in the PAR (derivation of worst case to be reflected in an Appendix in the PAR). In case the worst case does not result in a safe use, the worst case per animal group should be described in the CAR.
13.	<u>UK CA 5 – Prescribed emissions defined in Table 5.4 of the ESD</u> Several applicants have raised issues with regard to prescribed emissions (as percentages) from animal housing following specific applications (smearing, sprinkling etc.) as defined in Table 5.4 of the ESD for Insecticides for Stables and Manure storage No. 14 [ENV/JM/ MONO(2006)4]. **To be discussed:** Do MS consider that these fractions could be refined and, if so, what type of active or product related “data” would be needed to reduce such predictions?	**Point open.** PT 18 EG was inconclusive. A respective study would be very product specific and it is difficult to judge without knowing the study design. It is furthermore questionable if the result of one study could be used to generally change the emission fractions. Item to be further discussed by the ENV WG.	*ENV WG to follow up.*	The WG agreed that this item should be left open for the time being, it will be taken up again if concrete studies to reduce the prescribed emissions are provided in the frame of an application (AS or BP).
14.	<u>UK CA 6 - models for animal housing products used by amateurs (homeowners etc.)</u>	**Point closed.** The PT 18 EG propose to	--	The WG confirmed that there is no need

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	To be discussed: Do MS have any relevant models in order to address animal housing products used by amateurs (homeowners etc.) to assess products used in small pigeon lofts, dove cotes or for poultry kept in domestic gardens or allotments? How do we define a maximum area of the housing, quantify the degree of emissions likely to environmental compartments (as manure spreading to agricultural land is not likely) and set a number of birds / animals etc.?	await until an applicant will provide such an use and use the proposed esmission scenario provided by the applicant as basis for further developpements. No action would be needed for the time being.		to send the use to the AHEE to develop a respective scenario.

List of Attendees (Annex I)

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