WG-IV-2016

Final minutes

02 December 2016

Minutes of WG-IV-2016

19-23 September 2016

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

Minutes of Analytical methods and physico-chemical properties WG

WG-IV-2016 (19 September 2016)

1. Welcome and apologies

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

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

2. Administrative issue

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

3. Agreement of the agenda

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

Three additional agenda items were included under AoB:

- GLP requirement for the determination of physico-chemical properties
- Surface tension and viscosity for product authorisation
- Iodate/Iodide/Iodine

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 II 2016

Comments on the draft minutes were received as follows:

Silicon dioxide (as a nanomaterial formed by aggregates and agglomerates): FR

Silicium dioxide/Kieselguhr: applicant

The comments have been included in the updated draft minutes which were agreed by the working group members.

6. Follow up of previous working group meetings

6.1 Calcium hypochlorite (active chlorine released from calcium hypochlorite)

Following the APCP WG II 2016, an amendment to the reference specification was suggested by the eCA. The working group members agreed on this proposal in an e-consultation.

6.2 1R-trans-Phenothrin

The chair informed the working group members that, as requested in the opinion of 1R-trans-Phenothrin, the applicant provided to the eCA (Ireland) additional information about analytical methods and storage stability. An e-consultation was launched to receive comment on this reports. As no comments have been received the additional information is accepted.

6.3 Peracetic acid generated from TEAD and sodium percarbonate

The eCA presented an overview on the accepted reference sources fulfilling the criteria set for the reference specification. The data was collected as agreed at the WG V 2015 (Agenda point 7.1), to derive specifications, and some details are at a stage of re-checking or confirmation. It was clarified that the discussion on setting the reference specification will not be reopened.

7. Discussion on the active substances

7.1 Mixture of cis- and trans-p-menthane-3,8-diol (PMDRBO) PT19

All open issues were discussed and agreed by the working group members. The reference specification has not been set yet. Additional information about the specification is requested.

7.2 Fludioxonil PT07, 09, 10

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

7.3 MBIT PT06, 13

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

7.4 MIT PT11, 12

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

7.5 Cypermethrin PT18

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

8. Technical and scientific issues

8.1 AEM5772 – Analytical methods

The working group members discussed and agreed on issues related to the substance identity of the active substance and the suitability of the analytical methods.

8.2 Precursors of in situ generated active substances

The chair presented a thought-starter and informed the working group members about the on-going drafting of guidance for in situ generated active substances and their precursors. The working group members welcomed the initiative of ECHA and agreed to provide input for drafting the guidance. Member states are invited to provide their input via e-consultation.

8.3 Chemical similarity check – Metofluthrin

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

9. Any other Business (AoB)

9.1 Notifications according to Article 17 of the Review Programme Regulation and applications according to Article 93 and 94 of the BPR – a summary

ECHA provided a presentation of the outcome of the evaluation of the notifications submitted for taking over the role of participant according to Article 17 of the Review Programme Regulation and an overview of the submitted applications for approval of active substances according to Article 93 and 94 of the BPR. ECHA highlighted that applicants have chosen several evaluating member states for the same active substance. As a consequence of this a close cooperation of these member states is required for processing these dossiers.

9.2 Check list for the accordance check

The chair informed the working group members that the accordance check of the draft CAR conducted by ECHA will be performed in more detail to streamline and facilitate the peer-review process. A detailed check list has been developed which will be applied. This check list was presented to the working group members and will be made available to them for their use before submitting the draft CAR to ECHA.

9.3 Influence of the change of propellant gas

This topic was not discussed at the working group meeting. An e-consultation will be launched.

9.4 Additional items

- **GLP requirement for the determination of physico-chemical properties**

The working group members discussed the reliability of quality standards and agreed that ISO 9001 is not regarded as a sufficient quality standard for conducting physico-chemical properties. This should be considered in a future update of the guidance on information requirements.

- **Surface tension and viscosity for product authorisation**

  The surface tension and the viscosity are core data requirements for the authorisation of biocidal products. In this context the question was raised whether these information requirements can be waived. The working group members agreed that waiving is possible if a scientific based justification will be provided by the applicants.

- **Iodate / Iodide / Iodine**

The working group members were informed by the NL member about on-going discussion about the decision taken by the working group in 2015 whether iodate should be regarded as a stabiliser or not. The Netherlands will present a position paper with an alternative approach.

Minutes of Human Health WG

WG-IV-2016 (19-21 September 2016)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 22 participants present, of which six were core members and one alternate core member. One stakeholder observer was present for the non-confidential agenda items. Applicants were registered for their specific substance discussions.

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

2. Administrative issues

SECR gave a brief presentation on housekeeping and administrative issues.

SECR reminded that confidential documents should be provided only via the S-CIRCABC 'Submissions' folder and via R4BP 3.

Nominations for the Micro-organisms WG are requested by 31 October 2016.

A separate rapporteur will be reimbursed only when no core member of eCA is present, and reimbursement would not be made if there are no open points in the discussion tables.

3. Agreement of the agenda

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

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

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

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

The minutes were agreed without changes.

6. Discussion of active substances

6.1 Mixture of cis- and trans-p-menthane-3,8 diol (PMDRBO) (eCA UK) PT 19

The WG requested the applicant to provide QSAR analysis on developmental toxicity for components above the generic concentration limit for reproductive toxicity. The eCA may launch an e-consultation in case of a positive QSAR alert. The classification of the two products for eye irritation remained to be clarified bilaterally between the eCA and SECR. All points were closed.

6.2 Cypermethrin (eCA BE) PT 18

The WG requested the applicant to provide a developmental neurotoxicity study at least 6 months before the approval date of the active substance. The toxicological reference values, dermal absorption and exposure assessment were discussed. All points were closed.

6.3 Sodium hypochlorite, Calcium hypochlorite, Chlorine (eCA IT) – risk characterisation

The WG discussed and agreed on the remaining issues regarding local risk assessment and dietary risk assessment. All points were closed and the eCA will provide updated CARs by 16 November.

6.4 Chemical similarity check - Metofluthrin (eCA UK)

Open points were related to the specification of the new source and the toxicologically acceptable concentrations. All points were closed.

6.5 MBIT (eCA PL) PT 6, 13

Three remaining open points will be closed in an ad hoc follow-up. These are to derive the critical NOAEL and the reference values. The toxicological relevance of the impurities in the reference specification will be clarified in an e-consultation.

The remaining open points were closed. The discussion focused on performing the systemic risk characterisation for active substances that exert systemic effects only as secondary to the local effects.

6.6 MIT (eCA SI) PT 11, 12

The open points were related to ADI and ARfD derivation and to the need to estimate residue transfer to food from paper treated with the biocidal product.

It was considered appropriate to derive an ADI and ARfD, but the assessment of residue transfer to food was not considered relevant.

6.7 Fludioxonil (eCA DK) PT 7, 9, 10

Two remaining open points will be closed in an ad hoc follow-up. These are to derive the acute AEL and to conclude whether the batches used in the toxicological studies support the technical specification.

All other open points were closed. The discussion concentrated on toxicological reference values and absorption values, and several open points that were related to the exposure assessment for PT 7.

7. Technical and guidance related issues

7.1 Update on guidance development

SECR informed that Revised *Guidance on micro-organisms* was published in August 2016.

The CA consultation for *Vol V Disinfection by-products* will be launched shortly, and the publication is expected to take place in December 2016 or January 2017.

Regarding the guidance structure, ECHA considers that Vol III Part B contains also the parts that were earlier expected to be included in Part C. The file will thus be renamed as Part B+C; this will be done as a fast track consultation as no new guidance development is involved.

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

SECR informed that eleven recommendations have been agreed so far by the Working group and they are publicly available on the ECHA website, except one, for which the publication is foreseen after WG-IV-2016.

SECR gave an update on the activities of the HEAdhoc:

- The update of Recommendation no 6 “Methods and models to assess exposure to biocidal products in different product types - Version 2” is ongoing;
- The HEEG Opinion 12 “Harmonised approach for the assessment of rodenticides (anticoagulants)” and the HEAdhoc Recommendation no. 9 “Hand disinfection in hospitals by professionals – Inhalation and dermal exposure during hand disinfection” are under revision;
- The recommendation on the transfer coefficient for ConsExpo rubbing-off model is foreseen to be presented at the WG-V-2016;
- The recommendation on the spray study in slaughter house for high pressure disinfection is foreseen to be presented at the WG-I-2017;
- A recommendation will be developed based on the British Coatings Federation PT21 survey.

7.2(a) Recommendation “Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT 3)”

The recommendation was scheduled for agreement at the WG-IV-2016, but was not presented. It was therefore rescheduled for WG-V-2016.

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

SECR presented an update on the guidance development. A Partner Expert Group on the “Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses” will be established in October-November 2016 and a full ECHA consultation procedure will follow. The finalisation of the project is foreseen by September 2017.

The draft “Guidance on estimating livestock exposure to active substance used in biocidal product” will be published on ARTFood web page once agreed by ARTFood members. The scenario to estimate the biocidal active substance residue in milk due to teat dipping procedure will be developed as soon as possible and included in the draft document. The final draft will be commented by the CAs and ASOs in January-February 2017, pending the finalisation of the teat dip scenario. The publication of the final guidance document is foreseen by May-June 2017. The “Guidance on estimating transfer of biocidal active substance into foods – professional exposure” is still on hold until the CAs will agree with the approach on MRL setting for biocides (CA-March16-Doc7.2).

7.4 Principles for reopening TM/WG agreements

SECR presented the meeting document WGIV2016_TOX_7-4 and explained that the document would be discussed in all WGs and a common final document would then be prepared.

Several members commented that in their opinion the document should be either agreed by the BPC or at least brought to the attention of the BPC.

Only very minor modifications were proposed and the WG agreed on the document. A final version will be provided based on the discussions at the other permanent WGs.

7.5 Precursors of in situ generated active substances

SECR presented the meeting document WGIV2016_TOX_7-5. Following the WG discussion, a commenting period will be launched and, based on all input, SECR will prepare a proposal for WG-V-2016.

The representative of an Associated Stakeholder Organisation indicated that a formal objection had been made to the CA meeting document (CA-Nov15-Doc.5.5) referred to in the document. This objection questioned what is in the current document referred to as follows: “It is important to note that the precursors are also covered by the REACH Regulation (EU) No 1907/2006 and all related provisions (registration, evaluation, authorisation and restriction)”. The status of the objection and the related statement will be clarified in cooperation with the Commission.

One member stressed the importance of providing clear instructions to the applicants regarding the purity and impurities of the precursors.

It was discussed whether it can be concluded that if the precursor is not a substance of concern (SoC) and contains no SoCs, it could be concluded that no data requirements should apply. This approach was considered to be in line with the handling of biocidal products where a co-formulant would only be taken into account if it is a SoC. Not being a SoC does however not mean that a substance would have no toxicological effects and it was requested to clarify this.

One member considered that the starting point for data requirements should be to provide all available information, including study reports, harmonised classification and labelling, evaluations of regulatory bodies, possible read-across, QSARs etc. As the minimum, the data requirements for biocidal products were also supported, as indicated in Annex III to the Biocidal Products Regulation (BPR). In addition to the product data requirements, it was suggested to include an Ames test. Positive findings in these sources of information might then trigger further requirements that are described in BPR Annex II, noting however that waiving should be supported much more than it is for biocidal active substances.

One member considered that whenever sufficient information would be available to perform a meaningful risk assessment, this should also be performed regardless of e.g. the SoC status of the precursor.

One member suggested the possibility of applying the data requirements according to REACH Annex VIII, regarding substances manufactured or imported in quantities of 10 tonnes or more.

One key factor determining the data requirements is whether it is considered necessary to perform a risk assessment. The members strongly requested further input from the policy level to indicate what the objective would be. From the purely scientific viewpoint it would not be possible to decide which level of information would be sufficient and whether a full risk assessment is necessary or not.

7.6 Dermal absorption of antifouling products

SECR informed the WG of the workshop organised in May 2016 in Berlin, based on which the current document was drafted.

The members requested the possibility to provide written comments. Noting the available time for the meeting, SECR agreed to launch a commenting period, after which a revised document would be provided.

7.7 Technical issues related to renewal of anticoagulant rodenticides

Following the Biocidal Products Committee discussion on the renewal of anticoagulant rodenticides, a number of technical questions regarding the renewal of authorisation of anticoagulant rodenticides biocidal products were raised in the Coordination Group. These questions were then forwarded to the WGs for discussion.

The members generally supported the assumption that dermal absorption of second generation anticoagulants would be similar in a given formulation type, while it would be difficult to conclude on general principles between formulation types. As an example, it was not accepted that dermal absorption would always be lower from a wax block than from pellet baits, as was proposed in the meeting document. The members also considered it difficult to conclude on a worst case as this would depend on a number of variables that could be specific to each active substance.

FR presented the room document that they provided on applying a default dermal absorption value of 4 % for grain bait formulations. This approach was supported by several members, and it was considered possible to extend the analysis and provide a proposal for a similar default value for the different formulation types.

The documents on dermal absorption provided by UK and FR will be provided in a S-CIRCABC Newsgroup for commenting.

DE presented their written question regarding the approach for re-evaluating dermal absorption studies. As the discussion concerned the procedure, SECR considered this question to be out of the scope for the WG. The WG would however be the appropriate forum to discuss any re-evaluations of data and the WG would agree to do this.

7.8 Guidance on substances of concern (SoC) – CG question on revising the guidance

The WG considered the current concentration limit of ≥0.1 % to be a reasonable cut-off for SoC identification for active substances that act as co-formulant in the biocidal product.

The members also supported the current guidance in that a full quantitative risk assessment should be performed for active substances acting as co-formulants and identified as SoCs.

7.9 Derivation of ADI and ARfD

Some members suggested that ADI and ARfD should be derived for all substances if suitable data is available, because it may be difficult to foresee the circumstances where they will be needed. SECR reflected that because the product types are known for each substance in the review programme, it could be considered unnecessary to put effort in deriving reference values that will not be used.

The members requested the document to mention that an ARfD might not need to be derived because suitable information is not available or because relevant adverse effects were not seen following acute exposure.

It was considered necessary to indicate in which cases the reference values could have different values from those set by e.g. EFSA. This might take place for example if more/new information has become available or if the values have been set a long time ago using old guidance.

For the derivation of ADI and ARfD, the ECHA Guidance refers to the principles used for plant protection products, and therefore the document should not mention the ECHA Guidance for the selection of assessment factors. Regarding the derivation of ARfD, the OECD Guidance for the derivation of an acute reference dose (OECD 124) will also be referred to.

Written comments on the document are welcome until 14 October 2016. SECR has provided instructions for commenting after the meeting.

8. Any other business

8.1 Other information & lessons learned

SECR informed that a drafting group has been formed for the preparation of guidance on endocrine disruptors.

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

SECR requested the MSCAs to make an effort to reduce the numbers of open points in the updated RCOM. With large numbers of open points, it is difficult for SECR to provide a draft discussion table early enough for commenting by the eCA. For this meeting, some of the substances had up to 92 open points which is very challenging. It was considered that scheduling trilateral discussions should be avoided during July-August, or if necessary they could be extended by starting them earlier.

SECR also repeated the request to prevent redundant entries in the RCOM table by abstaining from repeating a point several times, and in case MSCAs have made repeated comments, group them and indicate by colour coding or other means which is the leading comment to be discussed. Furthermore, eCAs are asked to use continuous numbering and to combine different PTs in one RCOM table.

Minutes of Efficacy WG

WG-IV-2016 (21-22 September 2016)

1. Welcome and apologies

The Chair welcomed all participants to the 13th Efficacy WG meeting. There were 7 core members who participated in the meeting. In addition, 9 flexible members/alternates/rapporteurs and one ASO representative participated to the EFF WG meeting.

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

2. Administrative issues

ECHA gave a brief summary on the administrative issues.

3. Agreement of the agenda

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

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

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

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

The Chair informed that comments for the minutes of WG-III-2016 had been received from FR, NL, IE and EL. Regarding point 7.2 “Efficacy testing of treated articles – (health) claim matrix” ECHA had made, as requested by NL, a suggestion to clarify the sentence on the requirement of yeasticidal claims for health care and health care facilities. The EFF WG still regarded the issue unclear, so ECHA will cross-check with SE. The amendments made by NL under points 8.1. Teat disinfection and 8.3. Permethrin containing biocidal products were agreed upon. The EFF WG also agreed to remove reference to the BG cage test, and accepted some other minor changes.

6. Discussion of active substances[1]

6.1 Cypermethrin (eCA BE)

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

The EFF WG agreed on the evaluation of the eCA.

6.2 Fludioxonil (eCA DK)

There were three remaining open points concerning efficacy for discussion. FR and SI were concerned whether the efficacy of the active substance fludioxonil has been sufficiently demonstrated in the concentration used in the risk assessment. The eCA presented new results supplied by the applicant, with minimum inhibitory concentration values for 15 fungal species with the active substance fludioxonil alone and in combination with two

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

other active substances. The applicant pointed out that in the product three active substances with different modes of action are used. The EFF WG concluded that innate activity of the active substance has been sufficiently proven for active substance approval.

The second open point was a suggestion from SE that a general precautionary sentence of the occurrence of resistance and of performing a literature search on that should be added to the CAR. The eCA was in the opinion that for adding this kind of sentence there should be guidance available on how to perform the literature search, and the sentence should then also be added to all other CARs. The applicant shared his concern of the interpretation of literature data and risk benefit analysis. The EFF WG pointed out that that it must be a particular reason to include such sentence in the CAR, e.g. literature research shows specific concern. The EFF WG dit not consider necessary to add this sentence to the CAR.
The third open point raised by SI, concerning the efficacy of fludioxonil in the concentration used in the risk assessment, was connected with the first open point. The EFF WG concluded that fungicidal effect of fludioxonil has been shown for some strains at the concentrations used for the risk assessment.

6.3 MIT (eCA SI)

There were three remaining open points concerning efficacy. In the first open point FR questioned which one is the representative product for PT 11, ACTICIDE M 10 or ACTICIDE M 20, and in which concentration the active substance MIT can be considered efficacious. The eCA clarified that ACTICIDE M 10 is the representative product for PT 11, and this will be corrected into the CAR. The difference between curative (killing) and preventive (static) treatments and the required log reduction for both was discussed. SI clarified that MIT in PT 11 is used as a stabilising preservative, and there are no efficacy criteria available for such products. After consideration the EFF WG agreed that MIT has been shown to prevent bacterial and fungal growth, but not to be bactericidal or fungicidal in the concentrations tested. This is sufficient for proving the innate activity of MIT, but as stated in the CAR, cidal activity at the use concentration has to be demonstrated at the product authorisation level.

The second open point from FR was whether MIT for PT 11 can be regarded as bactericidal/fungicidal, or whether it should be regarded as bacteriostatic/fungistatic. As discussed in the first open point, the EFF WG concluded that MIT prevents growth of bacteria and fungi, i.e. the action is not cidal but static.

The third open point, raised by FR and FI, concerned the use of MIT for PT 12, and whether the concentration used in risk assessment is efficacious. The applicant explained that MIT is used as a slimicide in combination with other active substances, and the in use concentration came originally from a customer. The applicant also noted that the application was submitted 2008, and at that time efficacy testing was not done similarly as today. FR and FI pointed out that there is no data for MIT to be efficacious at the concentration used in the risk assessment, since even in the test with two active substances together, the lowest tested concentration of MIT is higher than this one used in the risk assessment. The EFF WG concluded an ad hoc follow up necessary. The applicant will have to prove efficacy of MIT in concentration used in the risk assessment.

6.4 PMDRBO (eCA UK)

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

The EFF WG agreed on the evaluation of the eCA.

6.5 MBIT (eCA PL)

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

The EFF WG agreed on the evaluation of the eCA.

6.6 Status of ongoing ad hoc follow-up: silver zinc zeolite (eCA SE)

The Chair informed the EFF WG that SE clarified that the applicant had submitted the testing proposal within given deadline, but due to technical problems the message had not reached the eCA. Now, however, new tests are on-going, and the results will be presented during the next WG EFF meeting.

7. Guidance

7.1 Guidance development

ECHA gave an overview of the status of EFF guidance. A PEG consultation has been launched for Vol II Efficacy Parts B+C Assessment and Evaluation, and a PEG meeting will take place 26 October 2016 in Helsinki. CA consultation is foreseen for December 2016, and publication for January/February 2017.

Some transitional efficacy guidance have been published this year: TG on PT1-5 (disinfectants) was published 31 May 2016, and the TG on PT 18/19 was published 16 September 2016. In 2017 Vol II Part A Information requirements should be updated to be in line with Parts B+C. In addition, PT5 guidance will be developed following the recommendations of the Disinfectants project.

ECHA also gave a brief overview on the Repellents workshop organised by the Austrian Ministry for Agriculture, Forestry, Environment and Water Management in June 2016 in Vienna. The proposal of the workshop was that PT18 and PT19 guidance should be developed separately and structured by target organisms. DE informed of their offer to organise a follow-up workshop in Berlin in March-May 2017 to facilitate the start of drafting PT19 guidance. The EFF WG members asked whether for practical reasons the workshop could be organised in ECHA back-to-back with the EFF WG meeting in March 2017. ECHA will check the room availability around WG-II-2017.

7.1.a Guidance on PT8: New appendix with explanations on Annex A of EN 599 (FR)

FR gave an overview on how the informative EN 599-1 Annex A (Durability of wood and wood-based products – Efficacy of preventive wood preservatives as determined by biological tests – Part 1: Specification according to use class; Guidance on re-testing after making variations in product formulation) can be used under the BPR. Examples where the Annex can be of help are e.g. dossiers where an activity is added or removed; dossiers with slight evolution in the formulation, and validation of the range of variation of each component in product families. European Wood Preservative Manufacturers Association (EWPM) which includes a member of the CEN TC38 are clarifying the sections of EN599-1 Annex A to prevent misinterpretations, and this work will be added as an appendix under the Guidance for efficacy assessment for PT 8. FR is finalising the Appendix, and it possibly will be discussed in WG-V-2016. The Appendix or a reference to it will be added to PT 8 guidance; in case a reference is added the Appendix itself will be placed on the EFF WG website. ECHA confirmed that if the amendment is a small part of the guidance document, it may possibly be added via a written procedure without a full PEG procedure.

7.1.b Guidance on PT11/12: presentation on the progress, interest of MS to participate (FR)

FR presented on overview of PT11/12 guidance development. FR is leading the revision of the guidance with support from Cefic. A consolidated claims matrix for PT11 and PT12 in the format used in PT1-5 guidance has been drafted. When the matrix is finalised the COM will be consulted to cross-check each claim and respective PT, and the MSs will be consulted for any missing uses. As soon as the draft guidance is ready, FR will organise a workshop after the commenting period, probably beginning of 2017.

7.1.c PT14 guidance on efficacy assessment – status report (ECHA)

The comments from ASO/CA consultation and EFF WG discussion have been implemented to the TG on PT14, including comments which should be specifically checked for correctness of the implementation. The revised draft guidance document with these comments will be sent for final check for EFF WG. As common understanding has not been reached on the

paragraph on resistance ECHA proposal is to put this paragraph in a separate box with a footnote explaining that this part is still under revision and this is not the final text.. Then this part would be revised and finalised next year when PT14 will be included into Vol. II Part B+C and for the time being PT14 guidance would be published as TG (November/December this year). NL proposed to include the guidance into Vol II now instead of publishing it as TG. It was agreed that the EFF WG members will also be asked to give their opinion on this proposition at the commenting round.

7.2 Efficacy of in situ generated active substances (ECHA)

ECHA presented the plans to develop a manual on evaluation of in situ generated active substances, and a summary of the answers to a questionnaire launched by ECHA in May 2016. The EFF WG was asked for an opinion on which data should be required for precursors of in situ generated active substances, and whether data according to Annex II of the BPR should be required. Different aspects and examples were discussed. The general conclusion of the EFF WG was that when considering efficacy of in situ generated active substances, the whole system should be considered, not the precursors separately. Therefore separate data requirements or efficacy data on the precursors should normally not be required. BE pointed out that they have required data on precursors in some specific cases (e.g. generation of performic acid from precursors formic acid and hydrogen peroxide, which are both also active substances).

The EFF WG was also asked for an opinion on whether the in situ generated active substance should be regarded to have two active substances if the precursor also has a direct efficacy effect. The EFF WG´s opinion was that in order to be able to conclude this efficacy data on the precursor would be needed, and this would be a regulatory question not to be decided in the WG.

DE pointed out that cumulative and synergistic effects should be also taken into account. NL and FR informed that CEN is working on the proposal how the efficacy of co-formulants should be tested.

ECHA concluded that when the first draft version of manual on evaluation of in situ generated active substances will be prepared the EFF WG will be consulted on it, possibly before WG-V-2016.

8. AOB

8.1 PT14: Applications for major changes with lower concentration of an active substance (FR/ECHA) – closed session

FR presented four examples based on the dossiers submitted as a part of the applications for a major change. In all applications new efficacy data packages have been submitted and the original concentration of the active substance was decreased below the specific concentration limit specified in the 9th ATP Regulation. In all dossiers FR identified some deviations from the agreed guidance:

1. The proposed concentration of the active substance: 29 ppm. Laboratory tests showed sufficient palatability and mortality. Field tests are sufficiently effective, however bait quantities tested in bait stations were higher than the amounts claimed. FR agreed with the proposed change under condition that new field tests according to the claims will be performed within 2 years, otherwise the authorisation will be cancelled.
2. The proposed concentration of the active substance: 25 ppm. Laboratory tests showed sufficient palatability and mortality but the exposure time was longer than 4 days and different for rats and mice. Field tests are sufficiently effective, however bait quantities tested in bait stations were higher than the amounts claimed. As the number of deviations is higher that in the previous example FR decided to stop the clock and requested new field tests according to the claims made.
3. The proposed concentration of the active substance: 25 ppm and decrease of a palatable agent in the formulated product. E-consultation was launched as there were

several deviations in the laboratory and field tests in relation to palatability, mortality, exposure time, quantities of poisoned bait and quantities tested in bait stations.

As a result of e-consultation only exposure time in choice test could be acceptable as a deviation. MSs were in the opinion that the palatability must be demonstrated and field tests should reflect the claimed application rate. In addition some concerns arised in relation to secondary poisonning, increase of rats population (long treatment campaign) and increase a risk of resistance in case such product would be authorised. In general decrease of the active substance in the biocidal product should be allowed only if efficacy of the product in question is showed with clear criteria.

4. The proposed concentration of the active substance: 25 ppm. Laboratory tests showed sufficient palatability and mortality, the exposure time was longer than 4 days and different for rats and mice and the amount of bait differed from the challenge diet. In the field efficacy is demonstrated, however bait quantities tested in bait stations were higher than the amounts claimed. Additionally in the tests, bait stations were controlled and refilled quite often. After discussions with MS new field tests will be requested according to the claims made.

Based on these examples a proposal for future approach was given by FR in relation to:

- laboratory tests:

  palatability - in choice tests it should absolutely be validated (criteria of 20 % should be met without exceptions) and the same amount of bait as well as challenge diet should be provided.

  Proposal for laboratory tests:

  - systematic comparison between lab tests with old and new formulation to check the increase of palatability (valid if a.s is the only change)
  - longer exposure time accepted only if palatability > 20 % and no signs of animal suffering

  DE proposed for the range of products from the same applicant to test only the product with the lowest palatability and in case it is still effective to extrapolate the result to all others (animal welfare reason). The EFF WG members were rather sceptic and indicated that there are not that many products on the market from the same applicant, so it would be very difficult to group them and test one product only. UK proposed to ask only for new field data, which shows how the product works in practice.

  Conclusion: In case of active substance decrease from e.g.from 50 to 25 ppm and taking into account that a complete efficacy data package for the ‘old’ formulation has been submitted including at least 20% of palatability in the lab tests, the EFF WG assume that the level of palatability remains the same in the new product and hence only new field tests should be required for the application for a major change. If the palatability in the ‘old’ formulation is lower that 20% the full data package (laboratory and field tests) should be submitted.

  DE offered to prepare a proposal to differentiate between different anticoagulant rodenticides. It will be circulated to the EFF WG members.

- field tests: efficacy must be demonstrated according to the claims for two reasons:
  - environnemental risk assessment takes into account the application rate per surface unit, then quantities applied in the field tests has to be considered,
  - in case of high infestation, bait stations should be checked and refilled more often than every 2/3 days or once a week.

  Proposal for field tests:

- quantities in bait stations must follow the label claims, particularly in case of an active substance decrease.

Conclusion: the EFF WG agreed with the FR proposal for field test

- resistance – as stated in the final report on RMM concentration below 0,03 % would be ineffective for all FGARs against fully susceptible populations of brown rats and house mice, and the SGARs bromadiolone and difenacoum would be ineffective against resistance strains of both species where they possess certain mutations of the VKORC1 gene.

  Proposal: RMM and resistance monitoring must be proposed and carried out.

  The EFF WG members indicated that resistance monitoring is not within the responsibility of the MSCAs. ECHA will contact COM to check what is going on with the proposal for resistance monitoring at EU level.

  Conclusion: Open issue, no conclusion at this moment.

8.2 Criteria for accordance check of the CAR – evaluation of active substances (ECHA)

A draft template of checklist for the accordance check (ACC) of the CAR was presented by ECHA. According to the EFF WG 'Function of the active substance' (Q1/part A) and 'Information on resistance' (Q10/part A) are important criteria, which should be checked during the ACC. 'Categories of users' (Q8/part B) should be removed from the template. 'Way of application' (Q2/part B) and 'Intended uses' (Q4/part B) were considered overlapping. For the general comments and conclusions the EFF WG proposed to add a question concerning the link between the efficacious concentration and the concentration used in the risk assessment. It was also suggested to add a question to both parts A and B checking that experimental data have been filled into efficacy Tables 2.3.1 and 7.1., and considered that if mode of action and resistance have been included in part A, they can be waived from part B. ECHA will check if the phrase 'Reference biocidal product' is correct or should be amended into 'Representative biocidal product' in part B and if questions related to the concentration of the active substance in the in-use formulation/product, application rate and frequency of application (Q6-8/part A), and the likely concentration at which the active substance will be used (Q5/part B) are in the right place. A question of whether the activity of the sole active substance, not in combination with anything else, has been concluded will be added to the general part. ECHA will amend the draft template according to the comments made by the EFF WG, and will present the updated list in WG-V-2016.

8.3 Efficacy concerns of personal repellent products (UK)

UK spotted some difficulties during evaluation of different repellents products. In many cases the tests, i.e. arm-in-cage tests are performed using different standards. The key thing, which has to be clarified is an accurate application rate used in risk assessment. In the opinion of the UK this rate should be demonstrated to be efficacious and associated with the given protection time. UK expressed a concern on decisions made by the other WGs, when the EFF WG was not informed/consulted.

EL noted that there are different available standards for arm-in-cage test and suggested to accept not only one standardized test protocol in the revised PT19 guidance, therefore all scientifically sound protocols should be accepted, especially WHO and EPA protocols. Although the methodologies are different the efficacy endpoints probably are the same. This assumption, however, is not supported by relevant literature data. In response to a question from BE for a repellent product supported by field and not arm-in-cage test, EL suggested that if a robust field test is provided, the simulated "arm-in-cage" test can be waived.

NL pointed out that the dose used in arm-in-cage test should not be used for the risk assessment, it does not reflect the real conditions but the worst case and probably it is overestimated. As for the time being there is no other possibility the arm-in-cage tests should be used. NL proposed to asked applicants to determine first the main application

rate for the product and then perform testing. It would be useful for the risk assessment as well. The EFF WG members agreed with the NL proposal.

FR indicated its concern that the model of the risk assessment does not use the efficient application rate. FR is trying somehow to link them together.

In general the EFF WG considered that new tests are needed in the future and we should discuss this at WG level. The EFF WG agreed that the impact assessment has to be done but in the wider scale but at first the test requirements has to be established. The possible discussion on impact assessment should take place at different level, possibly at the BPC.

ECHA will check internally with the HH WG if there are any issues which have to be addressed in the efficacy guidance.

8.4 Treatment of wine barrels by in situ generated sulphur dioxide (DE) - closed session

DE is evaluating an existing active substance sulphur dioxide generated from sulphur by combustion in PT 4. The efficacy data submitted so far is considered by the eCA as not sufficient to prove the efficacy of this *in situ* system. In this light, the applicant agreed to conduct new studies. The discussion focused on the submitted study design and required log reduction. The WG agreed to the study design but raised several issues to be clarified with the applicant, i.e. the realistic contact time, impact of the temperature increase by combustion on the target organisms, control with the extraction buffer, if water is used as a starting point or dry barrels are used, any effect depending on age of the barrels. It was also suggested to address different concentrations in the suspension tests.

The required log reduction was not specified by the EFF WG. In general it was suggested that any log reduction should be accepted in this case.

8.5 Guidance on conditions of reopening previously agreed issues (ECHA)

ECHA presented a document detailing the principles of reopening the agreements of Technical Meetings or Working Group meetings concerning the assessment of active substances. Three reasons for reopening are identified in the document: additional information has become available, new relevant guidance or methodology has become available, or a clear error is identified. In the Annex of the document specific principles for each WG can be listed. For the EFF part one reason is proposed to be added: new application rate used in the risk assessment, derived from a product having a different formulation than the representative one. UK suggested to include a sentence to the Annex explaining that when previous decisions are not directly relevant to the new uses, reassessment is needed to cover other situations. The EFF WG were asked to send further suggestions to be added to the efficacy Annex to ECHA.

8.6 Other information & lessons learned (ECHA)

ECHA informed that a new version of SPC editior will be released in October and only some amendments with reference to the target organisms will be done due to technical problems. Technical Agreements for Biocides need to be constatntly updated, ECHA will prepare a proposal for updating the current version based on previous EFF WG discussions. The EFF WG members were asked to include always WG FMB when e-consultation is initiated. ECHA has created a space on CIRCABC to upload all e-consultations.

With reference to the RCOM tables ECHA reminded the members to use continuous numbering, provide all product types in a single RCOM, instead of multiple files that often contain identical comments and clearly indicate if the respective point is open or closed.

Minutes of Environment WG

WG-IV-2016 (21-23 September 2016)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 22 participants present, of which four were core members, two alternate members and fifteen flexible members. In addition two rapporteurs where present in the meeting. One representatives from accredited stakeholder organisations was present for agenda item 7. Applicants were registered for their specific substance discussions.

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

2. Administrative issues

SECR gave a brief presentation on housekeeping and administrative issues.

SECR reminded that confidential documents should be provided only via the S-CIRCABC 'Submissions' folder and via R4BP 3.

Nominations for the Micro-organisms WG are requested by 31 October 2016.

A separate rapporteur will be reimbursed only when no core member of eCA is present, and reimbursement would not be made if there are no open points in the discussion tables.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the WG members to provide any additional items. No additional items were proposed. The Chair further indicated that due to parallel sessions, the planned order of the first four active substances was changed and that the agenda will be handled in a flexible way. The agenda was agreed.

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

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

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

The minutes were agreed without further changes.

6. Discussion of active substances

6.1 Fludioxinil (eCA DK) – PT 7, 9, 10

The Working Group members agreed on the evaluation of the eCA. The eCA can prepare the updated CAR and proceed to the Biocidal Products Committee.

Action SECR:

- Forward the following question to the **BPC/CA** meeting: Is the assessment of an indoor use sufficient (if only indoor use is claimed) or should always also an outdoor use be assessed in order to cover treated articles entering the EU market?

- Streamlining of the text in Vol IV Part B related to the correction of the tonnage in case a substance is applied in a formulation with the related text provided in REACH guidance R 16 (to be taken up in the revision of Vol. IV Part B).
- Clarification with REACH guidance: what needs to be considered as basis for the tonnage data for the derivation of the default vales, e.g. $F_{mainsource}$ (related to the previous point, also to be taken up in the revision of Vol. IV Part B).

6.2 Cypermethrin (eCA BE) - PT 18

There is one open point that will be closed in an ad hoc follow-up. This point concerns the recalculation of scenarios 1a, 1b, 1c and 1d and revision of Doc IIB and Doc IIC.

Action eCA: to prepare the *ad hoc* follow up in collaboration with SECR. eCA to update the CAR based on the outcome of the *ad hoc* follow up accordingly.

6.3 MIT (eCA SI) - PT 11, 12

There is one open point that will be closed in an ad hoc follow-up. This point concerns the adaptation of microorganisms in the on-site STP.

Action eCA: to prepare the *ad hoc* follow up in collaboration with SECR. eCA to update the CAR based on the outcome of the *ad hoc* follow up accordingly.

Action SECR: Send the following item concerning direct releases via air and soil via drift (PT 11) to the **AHEE**: AHEE to further evaluate which of both calculation methods applied for PECsoil in PT 11 following deposition from air should be chosen in the future (i.e. which fraction is considered as the correct one for the PECsoil calculation).

6.4 Mixture of cis- and trans-p-menthane-3,8 diol (PMDRBO) (eCA UK) – PT 19

There are three open points that will be closed in an ad hoc follow-up. These points concern the ready biodegradability of the active substance, a request of additional confirmatory data (e.g. log Kow) / refinement of risk assessment and the PBT assessment.

Action eCA: to prepare the *ad hoc* follow up in collaboration with SECR. eCA to update the CAR based on the outcome of the *ad hoc* follow up accordingly.

Action SECR:

- Forward the question to the **BPC/CA** meeting if the following proposed procedure is applicable in general for plant materials: For the PBT assessment the existing trigger value of 0.1% should be used for assessing constituents. For the risk assessment, as trigger value for preparing a risk assessment a value of 5% of the whole mixture (i.e. specification) should be used, based on the lower trigger value for relevant metabolites. If the PBT assessment shows major concerns for one of the constituents occurring below 5% (i.e. fulfilling two of the three criteria), a risk assessment should be also performed for this constituents).
- Add an entry in the **TAB** on a tiered approach for PT 19 concerning the treated surface: as first tier, the default value for treated surface from the ESD should be used for the risk assessment, as a second tier the value decided for the treated surface in the human health section should be used. The same tiered approach would apply for taking into account dermal adsorption.

6.5 MBIT (eCA PL) – PT 6, 13

There are two open points that will be closed in an ad hoc follow-up. These concern the assessment factor for the derivation $PNEC_{soil}$ and the groundwater assessment.

Action SECR: Forward the following question to the **BPC/CA** meeting: Is it possible to streamline the approach and assessment (specifically with regard to the $PNEC_{water}$ derivation) for all isothiazolinones at the renewal stage? Could they be e.g. handled at the

same time?

6.6 Chemical similarity check - Metofluthrin (eCA UK)

One point could not be concluded however sufficient feedback was provided by the WG to the eCA to proceed with the evaluation.

Action SECR: Prepare a proposal for the WG on how to deal with Technical Equivalent cases or Chemical Similarity checks in the future (e.g. via e-consultation of a dedicated expert group consisting of ENV WG members).

6.7 New endpoints for Etofenprox – follow-up e-consultation (FR) – PT 8

There are two open points that will be closed in an ad hoc follow-up. These concern the assessment factor for the derivation $PNEC_{soil}$ and the groundwater assessment.

Action FR: to prepare the *ad hoc* follow up in collaboration with SECR followed, after conclusion, by an update of the list of endpoints of the substance according to the agreed procedure.

6.8 Items related to rodenticides referred to the ENV WG by the CG (ECHA)

The main conclusions are provided in the following:

1. Groundwater assessment for rodenticides (including hot spot applications)

The WG was asked if they agree that the level of exposure of groundwater by active substances as well as relevant transformation products should be below the threshold criteria laid down in the BPR, even in so-called hot spot applications.

Conclusion: The WG agreed that a groundwater assessment should always be performed, even for PT 14 when only hot spot applications are considered (TAB entry).

2. Threshold for groundwater assessment for rodenticides products

The WG was asked if they agree that the specific Water Framework Directive drinking water threshold concentrations should be harmonised if the current 0.1 ug/l value is no longer considered appropriate.

Conclusion: The groundwater assessment should be performed according to Annex VI of the BPR (point 68) for parent and metabolites (TAB entry).

Action SECR: Provide both conclusions of the ENV WG to the CG.

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 Agreement of documents discussed at AHEE-1 (ECHA)

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

7.2a PT 8: Should the city scenario be used and replace current scenarios in the OECD ESD for PT 8? (NL)

The ENV WG confirmed the conclusion of AHEE-1 that there is no need to apply the city scenario for PT 8, neither as 'stand-alone' scenario, nor in combination with the storm-water scenario. One remaining open point coming from AHEE-1 was that for product authorisation, if a product is applied only by brushing, the potential release to the STP as well as the indirect release to the aquatic compartment is not covered (only direct release to soil and surface water). The ENV WG was therefore invited to discuss the need for a specific scenario to cover the release to the STP in case of in-situ treatments at the service life stage.

Conclusion: The ENV WG agreed that for the assessment of the release to the STP from in-situ treatment (service life stage) the noise barrier scenario should be used (TAB entry).

Action SECR (AHEE-1): Remove "PT 8" in the title of the city scenario and the "rainwater scenario".

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

The item was discussed at WG-IV-2016 as well as in a break-out session post-WG on 27 September 2016, however it was originally not scheduled for agreement. In the following the conclusions by the break-out group are provided:

1. Remaining amount of manure/slurry at the end of a storage period

Conclusion of the breakout group: It was agreed for the time being not to consider any remaining amount of manure in the tank when doing the calculation routines. However it needs to be checked if this is a realistic assumption.

Agreed actions by the breakout group: WG members / CEFIC to evaluate the national situation on what are typical storage periods for manure or what are typical fractions that could remain in the storage tank after 53 days?

2. 'Average time approach' vs 'Average quantity approach'

Conclusion of the breakout group: It was agreed to use 'Average Quantity Approach' to calculate the fraction of active substance in manure after degradation.

3. Values for Focus PEARL simulations

Conclusion of the breakout group: Point open.

NL agreed to correct the equations as proposed by DE, however this will be further taken up in the frame of the clarification on open items in the ESD.

Agreed actions by the breakout group: NL to prepare a proposal for revised equations.

4. Prescribed number of applications falling outside the grassland period

This item will be further discussed in the frame of the clarification on open items in the ESD, therefore no discussion took place at the WG meeting or in the frame of the break out group.

5. Timing of applications during a manure storage period

Conclusion of the breakout group: Reference was made to the conclusion of item 2 above, i.e.: It was agreed to use 'Average Quantity Approach' to calculate the fraction of active substance in manure after degradation.

6. Application methods for which manure degradation is relevant

Conclusion of the breakout group: The relevant scenarios as proposed in Table 1 of the recommendation were confirmed. Applications for which degradation in manure are relevant are: sprinkling, spraying and spraying by aerosols or fogging (please refer also to table 5.4 of the OECD ESD for PT 18).

7. Metabolites during manure storage periods

Conclusion of the breakout group: It was agreed that the paper of DE concerning metabolites in the terrestrial compartment once agreed can also be used for metabolites occurring during manure storage periods.

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.

9. Scenario degradation in manure for arable land

This item will be further discussed in the frame of the clarification on open items in the ESD, therefore no discussion took place at the WG meeting or in the frame of the break out group.

Overall action SECR: To send the conclusions of the break-out session to the ENV-WG for confirmation and to set up a (physical) meeting with a small expert group to further discuss items 3, 4 and 9.

Overall action NL: To revise the recommendation based on the comments received during WG-IV-2016 as well as the break-out session. Revised recommendation to be re-send to the ENV WG for agreement.

7.2c Items for clarification resulting from the ESD Excel sheet preparation (ECHA)

The ENV WG confirmed the conclusion of AHEE-1. One open item related to PT 1 was further discussed at WG-IV-2016:

Two MS noted that concerning the emission scenarios for disinfectants used in permanent installed private pools (TAB), Facut_rel and Fchro_rel are fractions and therefore dimensionless and the unit should be deleted. In addition, concerning, Table 3.7, p.25 of ESD RIVM 2001 (med sector-instruments: once-through): the equation to calculate Elocal3,water was proposed to be corrected as follows:

$$E_{local3,water} = N_{rep\text{-}max} * Q_{machine} * \mathbf{10^{-2}} * C_{disinf} * e^{-kdegdisinf * Trepl} / (1+F_{carry\text{-}over})^{Trepl}$$

It was agreed at AHEE-1 to reflect the correction in the TAB: the volume of solution in machine should be noted in litres (L) not in m^3 and the working concentration (Table 3.7) should be noted in mg/L. If noted in %, "10^{-6}" in the equation should be deleted (to be adjusted also in the Excel sheet).

DE further clarified as follows:

- if the working concentration is noted in mg/L → multiply with "10^{-6}";
- if the working concentration is noted in % → multiply with "10^{-2}";
- if the working concentration is noted as fraction → no correction needed.

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

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

7.2d Draft guide on PT 21 product authorisation (UK, NL)

At the WG meeting, specifically the analysis of regional pleasure craft marina scenarios was discussed, however the item was not scheduled for agreement.

Comments made during the WG meeting on the document prepared by UK:

NL noted that UK used occupancy as a parameter and not the number of berth, however the number of berth per harbour should also be taken into account. UK noted that they used the information of the Newcastle report, which uses the number of berth in each marina assuming 100% occupancy, which is however not in line with the setup described in the OECD scenarios. UK will further look into the number of berth and the occupancy, also taking into account information received by CEPE. So far, the maximum berth number per marina is used.

NL further asked when UK did the modelling, did they set all parameters to average? UK responded that all parameters were taken as the average in line with the Newcastle report. NL noted that the new MAMPEC version can be run in a batch mode, which could facilitate further simulations of different scenarios/marinas. UK noted the problem was to identify a single marina that represents a 90th percentile. NL noted that there preference would be to have only one marina to be assessed per surface water compartment (marine/freshwater), which should be a realistic reasonable worst case. UK confirmed that this would be the ideal case, defining a single marina for each region that represents the 90th percentile. The issue further was that the worst case identified within a certain marina was however not the worst case for the situation outside the marina, to be explained by the mixing/dispersion inside and outside.

NL further pointed out that - in case it is possible to run MAMPEC in batch mode- calculating a distribution of PECs from a defined set of marina's and taking the x-th percentile of this distribution as PEC may be a step forward. This could possibly circumvent the problem that defining one single marina scenario (for e.g. the North Atlantic area) that delivers a worst-case PEC for all substances seems difficult. NL also indicated that they would favour an update of MAMPEC that contains such a 'batch mode' option if this is currently not the case.

CEFIC provide further the following statement from CEPE: "*Given that 30.7 m^2 underwater surface area is the value agreed in the OECD scenario document for Product Type 21, and that mathematically, it is implausible that vessels this size could be reasonably maintained at a boat density of 1.38 per 100 m^2, such an amendment is considered over-conservative. In this instance, since the overall assessment already has many elements of conservatism built into other aspects, CEPE would propose that the average value proposed in the regional scenario document be retained. If this is not considered appropriate and a boating density is required, CEPE would suggest the original value proposed by ICOMIA, on the basis of their technical knowledge of marina design, be retained for the regional scenario assessments.*"

SE noted that they would have further comments which they will send directly to UK (concerning e.g. marina depth, the fact that there is no tide in the Baltic Sea and the different occupancies of the berth in the Nordic countries between summer and winter).

Action SE: To provide their comments to UK.

Action UK: Cross-check the scenarios with the newly released MAMPEC version and further look into the number of berth as well as the occupancy assumed. Liaise with e.g. SE on the maximum density difference per tide for the Baltic scenarios, which can be a very sensitive parameter.

Action SECR: To initiate e-consultation in case WG members would like to provide further information to the items raised in the document.

7.3 Open items on emission estimation/exposure assessment (ECHA)

SECR started by presenting the items in Appendix 2 of the discussion table, asking whether the WG would agree to send the following items to the AHEE:

- Revision of the ESD for PT 7 (e.g. inclusion of the formulation step, alignment of equations with A/B tables)
- Fixation factors in PT9-leather
- Area of the animal housing to be considered for the application in PT 18
- Land application interval and manure storage period in PT 18
- Removal processes in PT 10
- Concentration in soil in PT9-rubber-roof membrane scenario
- Applicability of AHEE recommendation on PT 18 for PT 3
- Conversion of surface area to volume when applying the b.p. by e.g. vaporizing or fogging for PT 2.

Conclusion: The WG agreed to send these items to the AHEE.

The following items of the discussion table were then discussed:

1. Harmonization of input parameter in PT1 (HH/ENV)

Conclusion: The WG agreed to use the values provided in the background section as first tier worst case values which can be revised if needed in the light of further experiences during the review of disinfectants.

Action SECR: to check with the contractor the proposed value in case two values are provided. In case average values are available, these should be preferably used.

2. Use of SWASH calculations for sediment (PT 3 - run off from soil)

Conclusion: The WG agreed that for now Focus Swash should not be used for the calculation of PEC in sediment. However the item will be forwarded to the AHEE for further evaluation following the discussion on sediment in the frame of the revision of Vol. IV Part B.

Action SECR: Item to be send to the **AHEE**. Reference was made also background document prepared by CEFIC for item 7.4 of the agenda (point 1: revision of Infobox 8)).

3. Scenario for disinfection of tools by dipping (PT 3)

Conclusion: The WG agreed to extend TAB entry No. 33 in TAB version 1.1 of June 2016by including the proposed scenario (based on the scenario for disinfection of footwear for veterinary hygiene; ESD for PT 3: Emission scenarios for veterinary hygiene biocidal products (JRC Scientific and Technical Reports, 2011, section 2.4.1). The number of days should remain 365, representing a worst case.

Action SECR: To extend the **TAB** entry accordingly.

4. Water volume in the reservoirs / tubs in hoof disinfection scenario (PT 3)

Conclusion: The WG agreed that the tub volume should not be changed (and remain 600 L). The WG further agreed that disinfection with mats should be added to the Manual of Instruction (under preparation in the frame of the disinfection project) and to the TAB: a default value of 60 L b.p./100 animals should be used. These values can be revised in the light of experience with disinfectants used in PT 3.
The number of disinfection events should not be changed (i.e. remain twice a day).

5. Development of standard surface areas for small-scale RTU products in PTs 2-4

This point could not be concluded.

Action SECR: to initiate an **e-consultation** on the proposed default surface areas for the RTU scenarios as well as the question if a scenario for RTU is also relevant for PT 3 on 26th of September with a two weeks commenting period.

6. Secondary poisoning

Conclusion: The WG agree with the proposal to use 50% of the local $PEC_{surfacewater}$ for secondary poisoning as worst case, instead of using the PEC_{annual}.

Action SECR: The related correction of the equation (as already done in R16) to be added to the revised **Vol. IV Part B**.

7. Phosphate immission standards in PT 18

Conclusion: The calculations based on phosphate standard will be provided separately as optional item in the ESD Excel sheet. For active substance approval, it is sufficient to provide in the risk assessment only an assessment based on nitrogen standards.

7.4 Discussion of selected proposed revisions of Vol. IV Part B (ECHA)

In the following only the conclusions and actions defined at WG-IV-2016 are noted.

1. Harmonisation of conversion factor dry to wet sediment (Infobox 8)/ consideration of organic matter content

Conclusion: The WG agreed that the proposal of UK for Infobox 8 should be included in the revised Vol. IV Part B. The comments made by WG members on the content of the UK proposal (see column C) will be forwarded to the PEG as background document. The WG further agreed that UK prepares text proposals for items A to D:

A. Sediment assessment trigger value
B. Accumulation in sediment
C. Trigger for AF of 10 when EPM is used
D. Freshly deposited suspended matter vs deeper layers

An e-consultation on the preliminary draft text already prepared by UK will be initiated post WG. In the frame of the e-consultation, WG members should express their opinion on if point D should be further considered in the guidance.

Action SECR: To initiate e-consultation.

2. PEC_{intial}/PEC_{TWA} comparison to $PNEC_{initial}/PNEC_{TWA}$ and calculation of initial PEC in soil after sewage sludge application

Conclusion: The WG agreed that option A (Single exposure or repeated exposure with ≤1 application per month) could be immediately be transferred into a text proposal to be included in the revised guidance.

The comments made by the WG members on option A and B (see Appendix 2 below, item 7.4, column c) will be taken into account by NL when preparing the text proposal. Concerning option B a stepwise procedure is proposed: if a proposal can be prepared before end of October, it will be included in the revised guidance. If not, the item will put on hold for the next revision.

Further items to be clarified are procedural aspects: If the risk assessment procedure changes drastically, the application date of the guidance needs to be discussed. It is to be clarified if the revised proposal needs confirmation by the CA meeting. In addition

harmonisation with R16 should be emphasised.

Action NL: To provide text proposal for Vol. IV Part B by 15 October (including check on option B).
Action SECR: To follow up procedural aspects

3. Differences in sludge rates in STP in guidance documents and models used for risk assessment of biocides

Conclusion: The current value in Vol IV Part B should be adjusted in line with the current agreed version of EUSES/SimpleTreat, i.e. SURPLUSsludge of 0.019 kg/d/inhab-eq. There are current inconsistencies in applying the SURPLUSsludge. Starting from WG-IV-2016 it is therefore recommended to use the value provided in EUSES until the revised Vol. IV Part B is published. However if CARs have been prepared already before WG-IV-2016 a certain flexibility should be applied in using the value provided in the current Vol. IV Part B.

Action SECR: To include the SURPLUSsludge proposal (0.019 kg/d/inhab-eq) in the **TAB**.

7.5 Additional emission scenarios for PT 2 prepared by DE (DE)

DE proposed emission (sub)scenarios for biocidal products under PT 2 with an intended use in aquaria, indoor fountains, and above ground small pools. Remaining open items following an e-consultation were discussed at the ENV WG meeting. The scenarios are provided in **Appendix 2** below.

1. Agreement of the new scenarios “aquaria” and “indoor fountain” for PT 2

Conclusion: The WG agreed to add the scenarios for disinfection of aquaria and indoor fountains including the corrections proposed at the WG meeting into the TAB.
In the light of experience, the default values may be adapted in the future.

2. Agreement of the new scenario “Disinfection of above ground small pools” for PT 2

Conclusion: The WG agreed to the proposed three new emission pathways of the scenario “Disinfection of above ground small pools” for PT 2 and their inclusion in the TAB. For the release via STP: In case permanent pools are not relevant and only above ground small pools are assessed, the scenario for permanent pools (for peak emissions) should be used and the default pool volume should be adjusted to the volume for above ground small pools (i.e. 14 m^3).

Action SECR: Both scenarios to be added to the **TAB**.

7.6 Precursors of in situ generated active substances (ECHA)

SECR presented a thought starter regarding the assessment and information requirements in relation to precursors used to generated active substances in situ relevant for approval of such active substances. It was clarified that the guidance is particularly relevant due to the number of notifications received for active substances generated in situ as a consequence of the article 13 of the Review Programme Regulation. SECR also explained that the thought starter proposes certain simplifications and stepwise approach in the assessment considering a number of complexities inherent to the assessment of in situ generation systems. It was highlighted that apart from technical questions there are also political issues to be agreed upon and therefore those may need to be resolved only at the BPC level.

NL highlighted that many precursors are general substances used elsewhere, having various suppliers but having plenty of quality information available from REACH databases. NL supported the idea of preparing a matrix database for precursors frequently appearing in the in situ active substance generation systems.

SECR invited the members to comment on the thought starter through an e-consultation and to volunteer in exchanging ideas on the assessment of in situ active substances. DE, UK and FI indicated its interest in providing informal feedback on the guidance during its further development.

Action SECR: To launch an e-consultation on the thought starter.

8. AOB

8.1 Other information & lessons learned

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

Concerning guidance related issues SECR informed that a drafting group has been formed for the preparation of guidance on endocrine disruptors with experts from the ED expert group, ECHA and EFSA. In addition SECR noted that the guidance on microorganism was published on the ECHA webpage and that the COMLEAM software, presented first at WG-I-2016 is available, workshops will follow next year.

SECR requested the MSCAs to make an effort to reduce the numbers of open points in the updated RCOM. With large numbers of open points, it is difficult for SECR to provide a draft discussion table early enough for commenting by the eCA. It was considered that trilateral should be avoided taking place during July-August, or if necessary they could be extended by starting them earlier.

SECR also repeated the request to prevent redundant entries in the RCOM table by abstaining from repeating a point several times, and in case MSCAs have made repeated comments, group them and indicate by colour coding or other means which is the leading comment to be discussed. Furthermore, eCAs are asked to use continuous numbering and to combine different PTs in one RCOM table.

It was finally noted that the submission window (for the draft CAR) should be followed for all substances, including draft CARs for which a formal accordance check is not needed. The reasons for this is that the quality of the documents provided was not always sufficient and adjustments may be necessary before upload for commenting. The accordance check period will be used for this purpose.

Additional “lessons learned” noted during the meeting:

- **SECR**: Check on alternative methods on how to deal with Technical equivalence/Chemical similarity cases, in case new endpoints are available for an active substance post approval follow the agreed BPC procedures, check the possibility to combine Vol. IV Part B and R 16 in the future.
- WG members: **SE** noted that discussions should take place when the LoEP should be updated at all (e.g. thresholds) – to be followed up with **BPC/CA meeting**. **DE** asked if it would be possible to include also bi-/tri-laterally closed points into the discussion table. SECR clarified that if bi-/tri-lateral closing takes place after the updated RCOM table, this is usually reflected as point for information in the discussion table. Items that are closed bi-/tri-laterally before, these are reflected in the updated RCOM table. In addition, WG members can still ask for re-opening closed points in the updated RCOM table in the week after it was uploaded, in case they do not agree to a closed point.

8.2 Guidance on conditions of reopening previously agreed issues

The document was agreed by the WG members, the following items were further raised:

- The principles laid down in the document should not apply to the renewal of active substances (a respective sentence will be added to the final version).
- A section should be included in the CAR template in which the items provided in the Annex of the “Guidance on conditions of reopening previously agreed issues” should be noted by the eCA.

Appendices:

Appendix 1:

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

Note:

- Issues unchanged since the previous WG meeting are highlighted in grey shading.
- Closed issues are ~~stroke through~~.

1. Guidance related documents

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

No.	Title (current leader)	Status
		DE prepared a proposal based on the work done so far by UK and included comments from the former SoC-WG, which was send to DK for a first commenting. DE included comments from DK into the guidance. Endorsement by written procedure was initiated on 10 June with a deadline for commenting until 29 July, comments were provided from FR, NL, UK, CH. **DE provided an updated version together with an RCOM table on 25 August 2016. SECR will include the revised version prepared by DE based on the comments received in Vol. IV Part B (biocidal product), to be further processed by the PEG.**
1.6	2nd EU Leaching Workshop for PT 8 (**ECHA**)	*Reminder:* ***Members*:** Start to perform a risk assessment for the new TIME2 (= 365 d), however not using it for decision making. Send the risk assessment to SECR via CIRCABC. ***SECR*** opened a Newsgroup on CIRCABC[2] in order to collect the data and perform an impact assessment as soon as sufficient data is available (target: in one year). **SECR** to include additional time also in the Excel sheet for PT 8 currently under preparation.
1.8	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)**.
1.9	1st revision of Vol. IV Part B (active substance) (**ECHA**)	1st revision: definition of subjects for first revision and assignment of volunteers taking over the subjects were agreed at WG-I-2016, revised text parts have been provided by 15 June 2016. **Specific items were discussed at WG-IV-2016, main discussion of the revised text will take place in the frame of the PEG.**
1.10	Guidance on aggregated exposure assessment (**DE**)	The discussion of the draft guidance is re-scheduled for an electronic procedure, **to be started in Q4 2016**.
1.11	TAB (**ECHA**): Technical Agreements on Biocides	The second revision of the TAB was initiated, version 1.2 will be distributed post WG-V-2016 for a six week commenting period.
1.13	ESD for PT 6 (**DE**)	DE has revised the ESD following comments received. **The ESD is scheduled for discussion at WG-V-2016.**
1.16	Guidance on disinfectant by-products (Dedicated WG)	The PEG written consultation is concluded, the CA consultation is planned to be launched on 19 September (4 weeks for commenting). **Publication foreseen in December 2016.**
1.18	Evaluation of ESD PT 14	Shortcomings of the current emission scenario document for rodenticides (ESD PT14) became obvious within the national product authorisation of rodenticides. UBA

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

No.	Title (current leader)	Status
		Germany has initiated a research project to review the described scenarios and assumptions. The project is scheduled from January 2016 to November 2017.

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

No.	Title (current leader)	Status
~~2.1~~	~~1. PT 6.1/ detergents/ Consumption based approach: amount of disinfectant for laundry The value to be used for the amount of disinfectant per kg of dirty laundry need to be harmonised~~ ~~2. PT 6/ Harmonisation of the daily emission from fabric washing (TGD IV value vs HERA value)~~	~~Outcome of the e-consultation was discussed at WG-IV-2015. Some open points were taken up in the frame of the ESD for PT6.~~ **The outcome of the consultation will be reflected in the ESD for PT 6.**
2.2	PT 6.3 / Pulp and paper processing fluids / Consumption based approach: use of 50% market share ⇒ *WG-II-2014 – item 6.4*	To be followed up under point 2.5.
~~2.3~~	~~Use scenarios for PT 9 roof membranes (prepared by DE): Discussion on if the correction of the equations provided in the (revised) OECD ESD for PT8 is also applicable for this guidance document~~ ~~⇒ *WG-III-2014 – item 7.4*~~	~~Taken up by DE and NL (in the frame of the meeting related to item 2.5)~~ **Was discussed at WG-IV-2016 in the frame of item 7.4.**
2.5	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*	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 on two items took place at WG-IV-2015. **Discussion at AHEE-1. Revised recommendation will be send to AHEE post WG-IV-2016 for commenting, endorsement of revised recommendation by ENV WG scheduled for WG-I-2017.**
~~2.6~~	~~PT 6.3/ Default value and application of Fbroke (currently 0.2) + correctness of the equation provided in the ESD~~ ~~⇒ *WG-I-2015 – item 7.1*~~	~~Outcome of the e-consultation was discussed at WG-IV-2015. One item will be taken up in the frame of the ESD for PT 6.~~ **The outcome of the consultation will be reflected in the ESD for PT 6.**
2.7	PT 18: How to derive values for the cleaning efficiency FCE (=> Release and exposure	AHEE member to take over item to be assigned.

No.	Title (current leader)	Status
	estimation of the biocidal product during cleaning step) ⇒ *WG-III-2015 – item 6.4*	
2.8	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. **Was discussed in the frame of item 7.3 at WG-IV-2016, followed up by a written commenting.**
2.9	PT 8: Use of a standard transfer factor (38 or 40) for transferring an application rate per volume to an application rate per surface (leaching rate assuming 100% leaching) or use of a specific transfer factor based on the dimensions of wooden commodity per scenario (of OECD ESD PT 8). ⇒ *WG-IV-2015 – item 6.2*	AHEE member to take over item to be assigned.
2.10	PT 8: Should the city scenario be used and replace current scenarios in the OECD ESD for PT 8? ⇒ *WG-IV-2015 – item 6.2*	NL volunteered to take over this point. **Discussion at AHEE-1, endorsed at WG-IV-2016.**
2.11	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.
2.12	PT 18: Development of equations to take into account degradation in manure ⇒ *WG-V-2015 – item 7.2b*	NL volunteered to take over this point. Discussion at AHEE-1, NL will provide revised document to SECR by 1 July 2016. **Discussion at WG-IV-2016, followed by a break-out session on 27 September 2016. Endorsement scheduled for WG-V-2016.**
2.13	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 – low priority for the time being
2.14	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).
2.15	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.

No.	Title (current leader)	Status
2.16	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.
2.17	Proposal on exposure assessment of metabolites in the terrestrial compartment ⇒ *WG-II-2016 – item 6.4*	DE will prepare a proposal for discussion. **Discussion at AHEE-1, endorsement scheduled for WG-V-2016.**
2.18	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.

3. Ongoing e-consultations (AHEE/ENV WG)

No.	Title (current leader)	Status
3.1	AHEE consultation on ESD PT 18 (household + professional uses) - bait box scenarios	Questions raised by NL in the frame of MR, consultation initiated on 15 September 2016 **Deadline for providing comments: 17 October 2016.**
3.2	Start of e-consultation on PT 21 (item related to dichlofluanid ad hoc follow up) ⇒ *WG-II-2016 – item 6.8/6.9*	The e-consultation will be started post WG-IV-2016.

Appendix 2: Detailed minutes on specific non-active substance related items

Item 7.5: Additional emission scenarios for PT 2 prepared by DE (UBA)

Introduction

DE is currently evaluating biocidal products for national product authorisation in PT02. The concerned applicant presented new uses (aquaria, indoor fountain, above ground small pools) for this b.p. in PT02. Currently, no harmonised scenarios are available for the intended use of the b.p in the relevant/corresponding ESDs for PT02 (EUR 25115 EN, 2011) and RIVM report 601450008 Supplement to the methodology for risk evaluation of biocides, ESD for PT 2 (van der Poel, March 2001). An e-consultation was initiated by DE (UBA) in July 2016 to develop and harmonise environmental emission (sub)scenarios for biocidal products under PT 2 with an intended use in aquaria, indoor fountains, and above ground small pools. DE received helpful responses from Ad hoc EE WG members: NL, FR and UK. Based on the received comments DE (UBA) prepared proposals for the inclusion of the three mentioned scenarios into TAB.

Following amended description and calculation for aquarium and indoor fountain treatment in PT2 is proposed to be transferred to TAB. Regarding the treatment of above ground small pools, all three emission pathways to the environment (via STP, direct onto soil and direct into surface water) should be considered. Therefore, the following description and calculation should be transferred to TAB:

Aquaria

The most likely use pattern for a worst-case situation is the widespread use of algal control products in domestic aquaria. The route of exposure to the environment is via the STP, following routine cleaning of the individual aquaria. Home aquaria range in size from 10 L to > 200 L depending on the type of fish being kept. For emission estimation, a 100 L aquarium as a common size is considered. The routine cleaning of the individual aquaria, which involves removal of 25 % of the total water volume, is carried out every 2 to 4 weeks. This corresponds to 1.79 % of the aquarium's water being replaced on a daily basis. For determining the local emission of a.s. in biocidal products used as algal control in aquaria (PT02), as a first step for environmental exposure assessment, the scenario is described in Table 1. In line with the nomenclature of the ESDs, Fwater represents the fraction released to the STP. For the fraction of water replaced, due to the specific application of the product, an additional parameter is introduced: F_{rep}.

Table 1 Input and output values of the local emission scenario for aquaria

Input and output values for local emissions of scenario a) – Aquaria				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Aquarium volume	$V_{aquaria}$	100	L	D
Number of aquaria per STP	$N_{aquaria}$	600		D
Fraction of water replaced due to product application	*Frep*	0.0179	d^{-1}	D/S
Conc. of a.s. in aquarium	$C_{aquaria}$		mg/L	S
Fraction of a.s. released to wastewater	*Fwater*	1		D
Market share	*Fmarket*	0.5		D *)
Output				
Emission rate to wastewater	$Elocal_{water}$		kg/d	
Formula: $Elocal_{water} = (V_{aquaria} \times N_{aquaria} \times Frep \times C_{aquaria} \times Fwater \times Fmarket) / 1{,}000{,}000$				

*) – according to TAB (PT2)

Indoor fountains

The standard recommendation given for indoor fountain placement is that only distilled water should be used. The use of distilled water, alongside regular cleaning prolongs the life of the pump. In a worst-case situation, however, the most likely use pattern for a biocidal product would be the widespread use of algal control products in indoor fountains. The route of exposure to the environment is via the STP, subsequent to routine cleaning by discarding the treated water via sewage system. The size of indoor fountains can range widely from tabletop devices (30 cm high) to floor fountains (2 m high), which can hold between 2 to 10 L of water. For emission estimations, a 10 L fountain as a common size is considered. Furthermore, it is assumed that 100 % of the fountain volume is replaced and discarded on a daily basis during cleaning. For determining the local emission of a.s. in biocidal products used for algal control in indoor fountains (PT02), as a first step for environmental exposure assessment, the scenario is described in Table 2. In line with the nomenclature of the ESDs, Fwater represents the fraction released to the STP. For the fraction of water replaced, due to the specific application of the product, an additional parameter is introduced: F_{rep}.

Table 2 Input and output values of the local emission scenario for indoor fountains

Input and output values for local emissions of scenario b) – Indoor fountains				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Fountain volume	$V_{fountain}$	10	L	D
Number of fountains per STP	$N_{fountain}$	600		D
Fraction of water replaced due to product application	*Frep*	1	d^{-1}	D/S
Conc. of a.s. in fountain	$C_{fountain}$		mg/L	S
Fraction of a.s. released to wastewater	*Fwater*	1		D
Market share	*Fmarket*	0.5		D *)
Output				
Emission rate to wastewater	$Elocal_{water}$		kg/d	
Formula: $Elocal_{water} = (V_{fountain} \times N_{fountain} \times Frep \times C_{fountain} \times Fwater \times Fmarket) / 1{,}000{,}000$				

*) – according to TAB (PT2)

Above ground small pools

These pools can be described as private temporary (summer only) swimming pools above the ground (see Figure 1).

Figure 1: Example for above ground small pools

These pools are expected to be completely emptied at the end of the summer season and stored over the winter months. Therefore, the season of an above ground small pool is one summer, in accordance with ESD for PT 19 this corresponds to 91 days. Draining of the pool water occurs through a valve in the pool wall or a hose over the rim of the pool. Drainage water can be released to the STP, nearby surface water, or adjacent soil.

STP: The emission pathway via STP is covered by the assessment for permanently installed private swimming pools described in the TAB, therefore a separate scenario for above ground small pools is not necessary.

Surface water: The direct emission of private temporary swimming pools to surface waters is likely to affect water bodies similar to the 'edge of field' water bodies described in FOCUS Surface Water[3]. Of the three water body types (pond, ditch and stream) defined in FOCUS Surface Water, a ditch is the most likely water body type to occur in the near vicinity of properties having private temporary swimming pools. This water body type occurs in four drainage scenarios of which the hydrological characteristics are given in Table 3.

Table 3 Hydrological characteristics for ditches in drainage scenarios in FOCUS Surface Water

Scenario	Discharge [L/s]
D1-ditch	0.008-3.88
D2-ditch	0.001-11.5
D3-ditch	0.08-0.71
D6-ditch	0.04-12.8

The average discharge for a ditch ($Flow_{ditch}$) in FOCUS Surface Water is therefore 3.63 L/s. With a pool volume (V_{pool}) of 14 m^3 and a

[3] FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC, EC Document Reference SANCO/4802/2001-rev2.

drainage time (t_{drain}) of 6 hours, the discharge from the pool ($Effluent_{pool}$) is 0.65 L/s. The dilution and local concentration of the pool water emitted to surface water is calculated based on equation 45 and 46 in the Guidance BPR IV Env B (2015):

$Effluent_{pool} = V_{pool} / t_{drain}$
$DILUTION = (Effluent_{pool} + Flow_{ditch})/Effluent_{pool} = 6.6$
$Clocal_{water} = A_{appl} / ((1 + KP_{susp} * SUSP_{water} * 10^{-6}) * DILUTION)$

Soil: The direct emission of private temporary swimming pools (14 m^3) to soil depends on the drainage time and the soils infiltration rate. Depending on the size of the valve or diameter of the hose, the time needed to drain the pool ranges from several hours to a day. For emission estimations, a drainage time (t_{drain}) of 6 hours as typical is considered. It is assumed that the exposed soils are fairly permeable, corresponding to a maximum infiltration rate (f_d) of 1 $m.d^{-1}$ (FAO, 1985, Irrigation Water Management: Training manual – Introduction to Irrigation, http://www.fao.org/docrep/r4082e/r4082e03.htm). The soil area exposed to the pool's drainage water is estimated according to the following equation:

$$AREA_{soil} = \frac{V_{pool}}{f_d * t_{drain}}$$

where $AREA_{soil}$ [m^2] is the soil area exposed, V_{pool} [m^3] is the pool volume, f_d [$m.d^{-1}$] is the infiltration capacity of the soil, t_{drain} [d] is the time needed to drain the pool.

For determining the local emission to soil of a.s. in biocidal products used in above ground small pools as part of PT02, as a first step for environmental exposure assessment, the scenario is described in Table 4.

Table 4 Input and output values of the local emission scenario for above ground small pools

Input and output values for local emissions of scenario c) – Above ground small pools				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Private pool volume	V_{pool}	14	m^3	D *)
Soil area exposed	$AREA_{soil}$	56	m^2	D (see above)
Soil depth	$depth_{soil}$	0.5	m	D
Bulk density of soil	RHO_{soil}	1700	kg/m^3	D
Application rate of a.s. in the	A_{appl}		mg/L	S

pool water				
Number of b.p. applications for one pool in the emission period	N_{appl}	1		D/S
Output				
Quantity of a.s. in pool water	Q_{pool}		kg	
Concentration of a.s. in exposed soil	C_{soil}		mg/kg	
Formula: $Q_{pool} = (A_{appl} \times V_{pool}) / 1000$				
Formula: $C_{soil} = (Q_{pool} \times N_{appl} \times 1{,}000{,}000) / (AREA_{soil} \times depth_{soil} \times RHO_{soil})$				

*) Common pool volume is between 7 to 14 m³ (according to investigation in DIY stores). Furthermore, in the discussion table – Summary of the e-consultation on scenarios to assess biocides as PT02 for private pool treatment (Conclusions of the WG ENV-I-2015), No. 4b. it is indicated: NL stated that inflated and metal frame pools have volumes of 10 to 14 m³ and will probably completely drained.

List of Attendees (Annex I)

Analytical methods and physico-chemical properties WG

Core members
MŰHLE Ulrike (DE)
WEBER Philippe (FR) – alternate member
LEFEBVRE Frederic (BE) Rapporteur
HUIZING Tjaart-Jan (NL)
HUSZAL Sylwester (PL) Rapporteur
WARBURTON Anthony (UK) Rapporteur
CEBASEK Petra (SI) Rapporteur
Flexible members
KORKOLAINEN Tapio (FI)
KARHI Kimmo (FI) Rapporteur
CATALDI Lucilla (IT) Rapporteur
THANNER Gerhard (AT)
FUERTES-LAZARO Pedro (ES)
SCHMIDT Marianne (DK) Rapporteur
TADEO Jose-Luis (ES) Rapporteur
Stakeholders
MARINER Richard (CEFIC)

Applicants
Sumitomo Chemical
Devan Chemicals NV
Euro Chlor
Arysta LifeScience Benelux
Thor GmbH
Dow
LANXESS Deutschland GmbH
TSGE consulting
Citrefine International Ltd
PAR / SCC
ECHA Staff
KREBS Bernhard (Chair)
AIRAKSINEN Sanna
GLANS Lotta
LISBOA MARTO Susana

Human Health WG

Core members
MAXIMILIEN Elisabeth (FR)
DE SAINT-JORES Jeremy (FR)
HOLTHENRICH Dagmar (DE)
KNEUER Carsten (DE)
NIKOLOPOULOU Dimitra (EL)
BRESCIA Susy (UK)
BOSMAN-HOEFAKKER Saskia (NL) - alternate member
Rapporteurs
LEFEBVRE Frederic (BE)
PETERSEN Annika Boye (DK)
UJMA-CZWAKIEL Monika (PL)
CEBASEK Petra (SI)
Flexible members
MIKOLAS Jan (CZ)
HAVSLAND Stine (DK)
VÄLIMÄKI Elina (FI)
HYVÄRINEN Tuija (FI)
HÄMÄLÄINEN Anna-Maija (FI)
REY Marion (FR)
HUSZAL Sylwester (PL)
FATUR Tanja (SI)
SANS-PICHE Frédéric (CH)
BUEHLER Dominique (CH)
Advisors
AXON Andrew (UK)

ECHA Staff
AIRAKSINEN Antero (Chair)
ANTAL Diana
ESTEVAN MARTINEZ Carmen
JANOSSY Judit
MYÖHÄNEN Kirsi
PECORINI Chiara
RUGGERI Laura
SCHAKIR Yasmin
Applicants
Sumitomo Chemical
Euro Chlor
SCC GmbH
KEMIRA
DOW
LANXESS Deutschland GmbH
Thor GmbH
Citrefine International Ltd
Arysta LifeScience Benelux
Stakeholders
COREA Namali – CEFIC (only for non-confidential items)

Efficacy WG

Core members
ATTIG Isabelle (FR)
MAXIMILIEN Yann (FR) alternate
GIATROPOULOS Athanasios (EL)
LEPAGE Anne (BE)
GERRITSEN Lonne (NL)
ESCH Daniel (DE)
HAMEL Darka (HR)
DUH Darja (SI)
Flexible members
VÄLIMÄKI Elina (FI)
VOGEL Birte (DK) - Rapporteur
JOHNSON Amy (UK)
BUEHLER Dominique (CH)
FISCHER Juliane (DE)
SANS-PICHE Frederic (CH)

ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
RAEZ-RUIZ Cristina
Applicants
Arysta LifeScience Benelux
THOR GmbH
Citrefine International Ltd
LANXESS Deutschland GmbH
Dow
Rapporteurs
DOLINSKA Tatiana (PL)
LEFEVRE Frederic (BE)
Stakeholders
GRUSON Bernard (CEFIC) – only for the non-confidential agenda items

Environment WG

Core members
LEFÈBVRE Frederic (BE)
ALEXANDRE Stéphanie (FR)
CHION Béatrice (FR)
PETERSOHN Eleonora (DE)
Alternate members
PACHITI Irene (EL)
OKKERMAN Peter (NL)
Flexible members
JENSEN Pia Haugaard (DK)
PASANEN Jaana (FI)
PENTTINEN Sari (FI)
FREIN Daniel (DE)
SETZER Sascha (DE) - Webex
SCHMIDT Jana (DE)
SCHNEIDER Julia (DE)
VAN-VLAARDINGEN Peter (NL)
SMIT Els (NL) - Webex
SYLWESTER Huszal (PL)
HAHLBECK Edda(SE)
PERSSON Johann(SE) - Webex
A MARCA Maria (CH)
WALTON Chris (UK) - Webex
HINGSTON James (UK)

Rapporteurs
CHRISTENSEN Anne Munch (DK)
HADAM Anna (PL)
VAN DER GEEST Bert (SI)
TAYLOR Christopher (UK)
Applicants
Arysta LifeScience
Citrefine International Ltd
Thor
LANXESS
Sumitomo Chemical
LODI
Dow
ECHA Staff
SCHIMMELPFENNIG Heike (Chair)
LAITINEN Jaana
LIPKOVA Adriana
NOGUEIRO Eugenia
SAEZ-RIBAS Monica
SCHAKIR Yasmin
WEBER Jan