Minutes of the Working Group meeting II in 2019 for Analytical Methods and Physico-Chemical Properties

(Meeting date: 19 March 2019)

28 May 2019

1. Welcome and apologies

The Chair welcomed the participants of the working group meeting. No accredited stakeholder organisation (ASO) was registered 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 issues

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

ECHA reported that a workshop dedicated to the active substance approval process with a specific focus on the Review Programme took place in February 2019. Representatives of member states competent authorities (MSCA), ASOs and Commission (COM) gathered for discussion about possibilities to improve the active substance approval process, in particular the evaluation and peer review steps, with a special focus on the Review Programme. Follow-up actions and proposal will be presented at the CA meeting in May 2019.

3. Agreement of the agenda

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

The following item was added to the agenda:

- Hydrogen peroxide and peracetic acid in biocidal products.

The agenda was agreed.

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

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

5. Agreement of the draft minutes from WG-VI-2018 and WG-VII-2018

Comments on the draft minutes were received as follows.

For working group meeting VI 2018

Comments were received from **Italy** on

- Bridging of shelf life;
- TE assessment when applying another legislation for reference specification;
- General agenda items

and from **Norway** on

- Ethylene oxide

For working group meeting VII 2018

Comments were received from **Belgium** on
- Contec IPA BPF UA;
- General agenda items

and from **Italy** on
- General agenda items

The draft minutes have been updated accordingly and distributed with the meeting documents. The Chair informed the meeting that in addition to the comments received by the members, ECHA revised editorially the minutes. The working group members agreed on the modifications. No comments on the other parts of the minutes have been received.

The minutes of the working group meeting VI and VII in 2018 have been agreed by the working group members.

6. Discussion of Union Authorisation applications

6.1. UA for product family Permethrin/S-Methoprene

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

6.2. UA for product family containing Octanoic acid

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

6.3. UA for product family containing Octanoic acid/Decanoic acid

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

6.4. UA for product family containing Hydrogen peroxide

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

7. Shelf-life decision tree

The updated shelf-life decision tree was presented, considering the working group discussions at APCP WG meeting V 2018 and the follow-up e-consultation. The working group members agreed to the updated shelf-life decision tree and agreed to include it in the Technical Agreements for Biocides (TAB) after the document is agreed at the Biocidal Products Committee (BPC) meeting.

8. Outcome of e-consultations

8.1. Biocidal products containing peracetic acid

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

8.2. Sodium orthophosphate

The Chair presented the outcome of the e-consultation for information; no discussion took place at the meeting.

8.3. Lavender extract

The Chair presented the outcome of the e-consultation for information; no discussion took place at the meeting.

9. AoB

Hydrogen peroxide and peracetic acid in biocidal products

The following issue was raised:

We are in the process of validating a union authorization biocidal product. In this family, the ratio of PAA:H2O2 is approximately 1:25. I am curious to know whether the working group would still consider H2O2 as a SoC only or that this is a ratio that would raise questions on whether H2O2 is an active substance. Complicating factor: contact times of 90 minutes using a fogging apparatus. PAA will be long gone before the end of the contact time and then the question is, will PAA be renewed quickly enough or will H_2O_2 take over?

The reason behind this question is probably obvious: if we go into the peer review and we get questions on this subject it would be nice to have a confirmation from the WG available that H2O2 should not be an active (as per the policy decision). If it *should* be considered as an active, then this application is in trouble. The only fortunate situation is that the whole family has a fixed ratio between PAA and H_2O_2, so we do not need to look for a threshold where H2O2 is or is not an active.

Discussion and conclusions:

A discussion took place whether hydrogen peroxide should be regarded as an active substance in addition to peracetic acid (PAA). It was clarified that peracetic acid is approved as an equilibrium between PAA and hydrogen peroxide and acetic acid (and water). Therefore, when manufacturing PAA, the ratio of each constituent in the equilibrium is not fixed, hence all possible PAA–equilibria are covered by the approval of peracetic acid. Hence, hydrogen peroxide can be present in the equilibrium with a high concentration compared to the concentration of PAA. However, in cases where hydrogen peroxide is added to a biocidal product that contains a PAA-equilibrium (as an active substance), the function of hydrogen peroxide has to be clarified.
In the specific case under discussion, the eCA should ask for clarification whether hydrogen peroxide is added to the biocidal product (in addition to the hydrogen peroxide of the PAA-equilibrium). If yes, its function must be clarified, whether it is an additional active substance or which other function is expected of added hydrogen peroxide.
The decision on the appropriateness of the proposed contact time is in the remit of the members of the efficacy working group and should be discussed at their meeting.

Annex 1 - List of attendees

Country	Members of WG
Belgium	VAN BERLO Boris
Belgium	LEPAGE Anne
Denmark	SKOU CORDUA Birgitte
Finland	KARPPANEN Essi
France	WEBER Philippe
Germany	MŰHLE Ulrike
Greece	TZANETOU Evangelia
Italy	CATALDI Lucilla
Latvia	IGAUNE Ieva
Norway	HELGERUD Trygve
Poland	HUSZAŁ Sylwester
Slovenia	VELIKONJA BOLTA Špela
Switzerland	AESCHBACHER Michael
The Netherlands	HUIZING Tjaart-Jan
United Kingdom	WARBURTON Anthony

ECHA staff
KREBS Bernhard (Chair)
GLANS Lotta
MATTHES Jochen
SCHAKIR Yasmin
VIEIRA LISBOA Duarte

Company	Observer
Ecolab	SCHRADER Eberhard
Ecolab	FORTH Peter
Sopura	VERSCHAEVE Stefaan
Sopura	VANDENBROUCK Tine

Accredited Stakeholder Organisations (ASOs)	
Organisation	**Observer**
-	-

WG-II-2019

Final minutes

28 May 2019

Minutes of Efficacy WG-II-2019

27-29 March 2019

Meeting of the Efficacy Working Group of the Biocidal Products Committee

Efficacy Working Group

1. Welcome and apologies

The Chair welcomed all participants to the 27th Efficacy WG virtual meeting. There were 5 core members, 2 alternate members, 12 flexible members and 3 rapporteurs who participated in the meeting. In addition 6 stakeholder representatives and the applicants were present for their respective agenda items.

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 information on the administrative issues.

3. Agreement of the agenda

The Chair introduced the agenda items. The EFF WG members agreed on the proposed agenda.

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

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

5. Minutes

DE had sent comments on the EFF WG-I-2019 draft minutes. The comments were agreed in their revised from by the EFF WG, and the revised draft minutes were agreed upon.

1. Discussion of Union Authorisation applications

6.1. UA for product family containing Hydrogen peroxide - PTs 1-4 (eCA LV)

There were 10 open points and 8 provisionally closed points in the discussion table, one of which was reopened in the meeting. Two points were closed during the meeting. To close the remaining issues an ad hoc follow-up will be launched.

6.2. UA for product family containing Octanoic acid/Decanoic acid - PT4 (eCA BE)

There were 5 open points in the discussion table. One point was left open to be closed in an ad hoc follow-up.

6.3. UA for product family containing Octanoic acid - PT4 (eCA NL)

There were 5 open points in the discussion table. Two points were left open to be closed in an ad hoc follow-up.

6.4. UA for product family containing Permethrin/S-methoprene - PT18 (eCA FR)

There was 1 open point and 1 provisionally closed point in the discussion table. The EFF WG agreed on all points.

2. Technical and guidance related issues

7.1. Vol II, Parts B+C – PT1-5, Appendix 4

For Appendix 4 - Overview of standards, test conditions and pass criteria (PT 1-5) altogether 91 comments had been received, and due to time constraints only a minor part of them were discussed. The Chair informed that the discussion will be continued in WG-III-2019.

Regarding specific discussions it was agreed to revise footnote 5 to make it clearer which EN tests refer to medical and which to non-medical applications for PTs 1 and 2. Clean/dirty soiling conditions were left for PT1 hygienic handrub and surgical handwash, but dirty conditions will be removed from surgical handrub, because in case hands are not visibly clean a prior handwash needs to be performed. It was also agreed to reword the heading "surgical hand disinfection" into "surgical handrub and handwash".

For hygienic handrub and hygienic handwash a footnote describing the three different levels of virucidal activity (virucidal activity against enveloped viruses / limited spectrum virucidal activity / virucidal activity) will be added. The option of using "full virucidal activity" instead of "virucidal activity" was discussed. It was agreed to use "virucidal activity" and discussed that Vol II B+C guidance is not consistent in the use of these terms, and should be revised using only "virucidal activity". Activity against fungal spores will be removed as irrelevant for all hand disinfectants. In addition virucidal activity will be removed from surgical handrub/handwash, with an explanatory note from EN 14885 added. Furthermore the contact times for PT1 tests for surgical handrub/handwash will be updated according to EN standards.

It was discussed whether the log-reductions for hygienic handwash should be amended according to prEN/fprEN standards. The issue was flagged for further discussion in May (WG-III-2019).

The proposal to amend the required log reductions for PT2 hard surfaces used in healthcare was discussed, but was not yet agreed upon.

7.2. Vol II, Parts B+C – draft guidance PT11/12

FR led this session, and started by reminding the EFF WG that the first discussion on the draft guidance for PT11/12 took place in WG-II-2017, and that the scope related issues on borderlines between different product types have been moved aside, waiting for a CA consultation to take place, planned for May 2019. Cefic representative introduced briefly industry views on the borderline issues. Three specific points were identified:

1. Into which PT (PT2 / PT11) *Legionella* control falls into. The industry (IND) considered that when the claim is on reducing infections, it would probably fall under PT 2.
2. When concentrates added to the process flow become process fluid additives – the borderline being between PT6 and PT11/12. Cefic view was that when a concentrate is added directly to the processing system, it would be PT11/12, whereas when materials are preserved during storage/transport without the intention of the preservative biocide to have further action in the process where it is added to, that is considered as preservative use (PT6).
3. Whether biofilm control falls into PT11 or PT12. Even the word slimicide is used, in most applications the real intent is not to remove biofilm (slime), but to prevent it from forming. IND finds it difficult to define that in PT11 applications part of the intent would not to be the control of biofilms.

For the draft guidance altogether 245 comments had been received. In this meeting the EFF WG discussed only the part related to PT11.

Regarding curative applications, IND proposed to change the wording into "corrective" applications. The EFF WG supported keeping curative, as it is used in the current guidance document.

The question of which laboratory efficacy tests and pass criteria should be used in order to be able to reliably connect the obtained efficacy data to real application rates required in the field was intensively discussed. IND explained that the ASTM E645 test currently being referred to in the draft guidance is quite flexible, and could probably be exploited by using shorter contact times (e.g. 1 h) for testing related to batch applications, and longer ones (e.g. 15 h) for testing related to continuous application. Integration of new, yet unpublished International Biodeterioration Research Group (IBRG) test method was proposed. One of the principal differences between the two methods is that in the ASTM test growth is not required in the controls, whereas in the IBRG method a growth increase by a factor of four is required in the control. It was also discussed whether individual organisms, a few species (e.g. one Gram- and one Gram+ bacteria) or larger consortia (8 species proposed in the IBRG method) should be used for testing. It was agreed that a written consultation of the testing and acceptance criteria will be launched, especially on whether for preventive claims growth in the controls of the efficacy tests should be required, and on which log reductions should be set as pass criteria. FR together with ECHA will coordinate the written consultation.

The EFF WG was of the opinion that there should be a separate section for biofilms in the guidance. It was also agreed that independent claims for fungi and yeast can be accepted, and some amendments were made to the test organisms presented in Tables 1 and 2. In addition testing and criteria for *Legionella* control were discussed; it was agreed that the contact time in the testing for continuous application can be changed from 15 h to 20-24 h due to practical reasons.

FR will revise the draft guidance according to the agreements made. The next WG discussion of the draft guidance is foreseen for autumn 2019.

7.3. Vol II, Parts B+C – draft guidance PT19

Three issues were discussed during the meeting. Two of them were related to lastly finalised e-consultations: on mosquitos – AIC simulated use test and mortality, respectively and the third one discussion was devoted to ticks.

Mosquitos – AIC simulated use test

With reference to mosquitos – AIC simulated use test several questions were left open after the previous discussion in December 2018. Based on the remaining questions and comments received AT prepared a working document and led the discussion. The EFF WG agreed that:

- Mosquitos from the three genera, i.e. *Aedes, Culex* and *Anopheles* are suitable surrogate organisms for the tropical claim. Respective strains from tropical regions should be chosen by the applicant and justified;
- Testing should be performed at 27°C (+/- 2C) and relative humidity of 75% (+/- 5%);
- To determine the CPT landing was accepted as a value for control tests and probing for treatment;
- CPT should be calculated prior to the first confirmed event;
- In case of general claim against mosquitos the lowest mean/median CPT over all tested mosquito species should be considered, in case of specific mosquito species claims, different CPTs for each of the claimed species should be considered;
- Starvation phase prior to the test was considered as not necessary;
- 10 to 8 (if 2 fail) volunteers was agreed as the minimum number of individuals tested;
- Regarding acceptable or not-acceptable claims this issue will be summarised by AT based on comments received and forwarded to the CG;

Mortality

Regarding mortality the EFF WG agreed that for vertebrates mortality due to some unexpected accidents during trials might be acceptable, but mortality in the treatment group should be similar to the control group and neither group should exceed 10%.

For invertebrates mortality during tests is acceptable, nevertheless for the intended use mortality in the treatment group should be similar to the control group. Deviations are acceptable and, if mortality will exceed 10%, justification from the applicant is needed. Field trials to prove mortality can only be used, if the observed population size can be exactly determined before and after the trial. Any observed mortality during the trial should be mentioned.

Ticks

With reference to ticks, in total more than 250 comments were received. Some of them were already incorporated by DE into the second draft guidance. The EFF WG agreed with most of the comments. With reference to development stage of ticks and necessary efficacy tests DE will cross-check internally, if for general claim against ticks only nymphs (as the most aggressive), adults, or both should be tested. Feedback will be given to the EFF WG.

4. AOB

8.1. Outcome of e-consultations

8.1a Growth quantification or determination of filamentous fungi (FR)

FR presented the e-consultation and the comments received. The acceptance of colony forming unit (cfu) counts for quantifying filamentous fungi in non-filterable matrices was intensively discussed. The EFF WG agreed that cfu counts is not an optimal method to quantify filamentous fungi, and noted that there are differences in how the current Vol II, Parts B+C guidance is interpreted in this respect. Most of the EFF WG members were willing to accept cfu-counts for the time being, because it is a tool well-known by the laboratories and often reported in the applications received so far. Some members objected to accepting cfu counts for filamentous fungi, but supported rather always asking for other methods, e.g. visual evaluation (microscopy). Nevertheless after discussion the EFF WG agreed with the proposal of FR, i.e. that with robust justification cfu counts can be accepted for quantifying filamentous fungi in non-filterable matrices. Only DE disagreed with such solution.

It was agreed that in the next update Vol II B+C guidance should be revised concerning this issue. FR will prepare a proposal.

8.1b Paint layer thickness in static raft tests (NL)

NL introduced the revised conclusion based on comments received from DK. The conclusion stated that raft tests are not designed to assess the efficacy of a particular thickness layer of a paint, but only whether the product is efficacious as long as a paint layer is still present on the treated panels. In the future update of PT21 efficacy guidance the principles and goals of raft testing should be clearly explained.

FR pointed out that application rate needs to be given in the SPC, and there needs to be a way to assess it. FR proposed to have the same approach as for disinfectants:

- Only use-concentration of product is validated in the raft test, e.g. 100% ready-to-use (or a % dilution if claimed);
- Product is applied in the raft tests at the application rate recommended by the applicant (expressed in m²/L of paint);
- Instruction of use should be added such as *"Apply the product uniformly on the surfaces to be treated at the application rate recommended so that efficacy is ensured during at least single fouling season"*.

It was agreed that NL will revise the conclusion according to the suggestions of FR.

8.1c Efficacy assessment of hatching eggs (DE)

The e-consultation was introduced by DE. Regarding the first question the EFF WG agreed that adapted NF T 72-281 method is suitable for a biocidal product that is intended to be used for disinfection of hatching eggs and applied by fogging/airborne diffusion.

The second question concerned the issue that even though eggs are porous, this method is designed for non-porous surfaces. The EFF WG agreed with the DE draft conclusion, noting that eggs should be added to the testing space.

The EFF WG also agreed on the third DE draft conclusion on test conditions (room size and temperature).

8.2 Other information and lessons learnt

The Chair informed that the next EFF WG meeting will take place 27-28 May, it will be a physical meeting in Helsinki. In addition back to back to the EFF WG meeting a PT19 workshop on 29 May will be organised.

To prevent final documents awaiting publication SECR has created a place on publicly available part of CIRCABC where documents agreed at WGs level will be placed. Date of uploading of final document is equal to publication date. SECR will prepare a list of documents agreed at EFF WG meetings and upload them there.

List of Attendees

Efficacy Working Group

Core members
ATTIG Isabelle (FR)
DUH Darja (SI)
GIATROPOULOS Athanasios (EL)
POULIS Joan (NL)
STRONG Colin (UK)
Alternate members
GUNNEWIG Kathrin (DE)
MAXIMILIEN Yann (FR)
Flexible members
MEZULE Linda (LV)
BALDASSARRI Lucilla (IT)
FISCHER Juliane (DE)
FONNESBECH VOGEL Birte (DK)
GURBA Alexandre (CH)
KAUKONIEMI Sanna (FI)
KRÜGER Martin (DE)
NIEMINEN Timo (FI)
PEČÍNKOVÁ Martina (CZ)
PEELMAN Natania (BE)
RYDMAN Elina (FI)
ZUTZ Christoph (AT)

Advisors
GĄSZCZYK Małgorzata
Rapporteurs
IGAUNE Ieva (LV)
LEPAGE Anne (BE)
RAT Benjamin (FR)
ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
STASKO Jolanta
SCHAKIR Yasmin
Applicants
Agrobiothers
Ecolab
HYPRED SA
SOPURA
Stakeholders
KASURINEN Ossi (Cefic)
THEELEN Meredith (expert)
ASHWORTH David (expert)
GRUSON Bernard (expert)
MORENO Mara (expert)
VAN SLOUN Petra (expert)

Environment WG-II-2019 & PT 8 EG meeting
Final minutes
15 June 2019

Minutes of Environment WG-II-2019

& PT 8 Expert Group meeting

27-29 March 2019

Meetings of the Environmental Working Group of the Biocidal Products Committee

Environment WG-II-2019 (28-29 March 2019)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 23 participants present, of which four were core members (one represented by alternate), fifteen flexible members and three rapporteurs. One representative from accredited stakeholder organisation was present part time. Applicants were registered for their specific substance discussions.

Participants were further 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.

2. Administrative issues

SECR gave a brief presentation on administrative issues.

3. Agreement of the agenda

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

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

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

5. Agreement of the draft minutes from WG-VII-2018

The minutes of one active substance and the general minutes were agreed via written procedure before the WG meeting.

6. Discussion of Union authorisations

6.1 UA for product family containing Hydrogen peroxide (eCA LV) – PT 1-4

Seven points were discussed, three items will be followed up by an ad hoc follow up.

Actions:

- **SECR** to initiate the ad hoc follow up.
- **SECR** to collect in general questions for clarification regarding SoCs. The WG discussed whether Annex I active substances should be considered as SoC. Also the WG discussed whether active substances for which a draft final CAR is not available and which are not present at a concentration leading the product to be regarded as hazardous should be considered as SoC.
- **SECR** to prepare **TAB entry**: For rapidly reacting substances (to be discussed on a case by case discussion if a substance is rapidly reacting, e.g. substances reacting with organic matter) no groundwater assessment is needed since it is very unlikely that any substance will reach the groundwater. To be confirmed by the **BPC**.
- The item groundwater limit value for inorganic substances will in general be taken up at the next **AHEE** meeting. **DE** volunteered to prepare a thought starter.

6.2 UA UA for product family containing Octanoic acid/Decanoic acid (eCA BE) - PT 4

Four points were discussed. All points were closed, the PAR can proceed to the BPC.

Actions:
- **SECR** to follow up internally on the Annex I entry of one substance.
- **SECR** to prepare a **TAB entry** for inclusion of the release path via manure in the ESD for PT 4 (scenario disinfection of milking parlours).

6.3 UA for product family containing Octanoic acid (eCA NL) - PT 4

Eleven points were discussed. All points were closed, the PAR can proceed to the BPC.

Actions:
- **eCA** to check the correctness of the value for Temission.
- **SECR** to include the emission scenario for disinfection of separative membranes in the **TAB**.
- **SECR** to prepare a **TAB entry** for inclusion of the release path via manure in the ESD for PT 4 (scenario disinfection of milking parlours) – see also agreed action for item 6.2 above.
- **eCA** to evaluate if one co-formulant does not need assessment according to the UK document trigger values for groundwater assessment and to assess ocatnoic acid for groundwater using a higher tier FOCUS model, simulating only the worst case scenario.

6.4 UA for product family Permethrin/S-Methoprene (eCA FR) – PT 18

Four items were discussed. All points were closed, the PAR can proceed to the BPC.

Actions:
- **SECR** to add the conclusion on the simultaneity factor to the **TAB.**

7. Discussion of Active substances

7.1 DBNPA ED assessment

One item concerning population relevance was discussed. The point was closed, the CAR can proceed to the BPC.

7.2 Feedback on ongoing & finalised substance specific e-consultations

SECR presented a summary table on the currently ongoing and recently finalised substance specific written consultations. One a.s. related ad hoc follow-up was finalised in January (metofluthrin PT 19) and three follow-ups are open (monochloramines generated in situ, transfluthrin and permethrin).

Actions:
- **SECR** to inform WG on the progress of the on-going consultations and coordinate necessary follow-up actions (Webex meetings and WG discussions).

7.3 Pyrethroid metabolites harmonised LoEP – update

SECR summarised what had happened so far and informed the WG on a discussion paper related the derivation use of DT50 data for metabolites and a respective e-consultation to find agreement on the correct use and choice of studies for metabolites' DT50 data.

Actions:

- **SECR** to share the list of endpoints file to allow the contributing MSs a review of the

input.
- **SECR** to start an e-consultation on metabolite DT50 data.

8. Technical and guidance related items

8.1 Overview on guidance (HS)

The Chair updated the WG on the PT8 EG meeting that took place on 27 March 2019. The conclusion of the EG meeting will be presented to AHEE/ENV WG at WG-III-2019 for agreement.

SECR further 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 2** below).

8.2 Outcome EPM project

SECR informed the WG on the outcome of the EPM project to predict toxicity to soil organisms. The project was launched in September 2016, in collaboration with different partners and focus it's the applicability for both Regulation REACH and BPR.
Results of the project are consistent with other literature studies on EPM, highlighting the importance of good quality of the data and improving the further development of alternative methods. Potential areas for further research were identified.
No questions from the WG were posed. The presentation is available in **Appendix 3** of the minutes. The project will be presented at the SETAC conference (2019) and the project's report will be published on the ECHA website in June approximatively.

8.3 RMM for bees

CH MSCA together with the Chair summarised the outcome of the 2nd e-consultation and the related issues/open points. CH CA reminded that there is no current guidance on risk assessment for bees nor agreed RMM for bees. The proposal discussed during the current WG would be presented to the CG who will ultimately agree on the final wording and feasibility of the RMM. Therefore the Chair clarified that the WG could collect comments and reflect on the impacts of the proposed RMM on bees but a final agreement by MSs was not necessary.

The proposal of the second e-consultation round was not fully revised due to the extensive number and heterogeneity of comments from MSs. Three main sections were discussed.

a. <u>agreement on the warning sentence for insecticidal biocidal products on potential hazard to bees and the proposed Tiered approach</u>

In terms of the wording of the sentence most of the MSs agree to replace the word "toxic" with "dangerous". Several comments were raised also in relation to the second part of the sentence but no agreement was found. There were several comments in relation to the data set used to be used for the derivation of the cut-off value proposed (LD50) and on the potential impact that could have on the generation of new information. Also the possibility to use a pictogram for bees as its being discussed for PPP was discussed. The WG agreed to keep working on the sentence and the cutoff asking also support from EFSA, and MSs' Experts on PPPs.

Conclusion: The Chair proposed to CH and DE MSs to collect the WG comments and try to provide a new compromise sentence. In regards to the cut-off and the endpoint to be used further discussions are needed in order to find alignment as much as possible with PPP.

Comments proposed:

- replace the word "toxic" with "dangerous";
- take off or make short the second sentence.

Action: CH and DE will provide options of the second part of the sentence, based on the WG comments. ECHA will consult EFSA PPP's experts to clarify the status of their discussions and try to align if possible.

b. agreement on proposed RMMs for outdoor uses of insecticidal baits for household and professional uses

CH presented the revised table on the RMMs developed after the first e-consultation and reminded that some added sentences are already used under the biocidal product regulation. WG did not fully agree on the new sentences proposed (marked in blue) since considered them confusing and in some cases not relevant (e.g. "*Do not apply the product if rain is expected within 24 hrs*"). Moreover, the MSs did not agree with the proposal to restrict the use of pouring agents and granules only for professional users. Some MS commented (FR, UK, NL) that the proposed RMMs should be discussed with the efficacy experts as the RMM may challenge the efficacy of the product. Specfically in regards to the RMM "*…in crack and crevices with a diameter of up to a maximum of 5 mm*", FR underlined that the sentence was provided by the applicant for a specific type of use and could be feasible, nevertheless it was challenged whether this measure would protect all bee species.

Conclusion: The WG agreed to the generic RMMs that can be applied for both users without distinctions. The new sentences marked in blue will be deleted.

Action: CH and DE will prepare a revised table on RMMs. The table will be available for MSs for a quick revision (via e-mail) before the submission to CG. A WebEx meeting will be organised. The possibility to give the access to the meeting also at the applicant will be taken into account.

c. agreement on proposed RMMs for use of insecticides in stables

CH explained that the revised RMMs were proposed in line with the RMMs already used to reduce the risk to other environmental compartments such as water or soil (such as the restriction to be used in cardboards). According to CH and DE these measures seemed to be applicable also as risk mitigation measures for bees. Nevertheless the WG had doubts on whether these measures would actually reduce the risk to bees. UK CA asked for the removal of the sentence "*Do not clean equipment with water, but dry-store, reuse, or dispose of used equipment to dry waste*" as this could be hazardous for human health. Some MS commented that the proposed RMMs should be also discussed with the efficacy experts. The WG highlighted that it would be very difficult to give informed advice on some of the RMM without a guidance on risk assessment for bees.

Conclusion: Generic RMMs will be presented to the CG waiting for more detailed guidance on risk assessment for bees.

Action: CH will provide a re-word of the RMMs (marked in blue) considering the comments of the WG. ECHA will try to find out more information related to the guidance on bees, contacting also the PPP's experts.

9. AOB

9.1 Other information & lessons learned

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

Next ENV WG meetings is scheduled for 22-24 May (physical meeting).
Next AHEE is planned for September 2019.

New open public CircaBC site: Path: /CircaBC/echa/Documents agreed at BPC WG meetings/Library
Link: https://webgate.ec.europa.eu/s-circabc/w/browse/845c07a2-b0d1-49c5-9620-90a037c6d1e4
The site contains final WG documents to prevent pending documents awaiting publication e.g. via TAB, the date of uploading of final documents (publication date). For completeness, earlier agreements have been included. It contains further the final minutes.

Endocrine disruptors: Link to publicly available information on ED EG substances: https://echa.europa.eu/ed-assessment
Provisional ED EG meeting dates 2019:

4-6 June
1-3 October
3-5 December

The meetings may be shorter depending on the number of substances. ED EG members are mostly from REACH, MS were invited to consider whether they could provide an ED EG member.
The next ED EG meeting takes place on 4-6 June:

- Deadline for confirming the substances: 9 April
- Confirm by email to ed_eg@echa.europa.eu

Endocrine disruptors – products
Assessment of ED properties of co-formulants in biocidal products – draft instructions for applicants: the UK document was agreed at CG-34 (12-13 March) with minor changes, the final document is not yet available
Another document will follow: instructions for MSCAs, to be prepared by FR. An e-consultation in CG expected to be launched in April.

In situ generated active substances
The document **"**CA-March19-Doc 4.5 Management of product authorisation for in situ cases" is available in S-CIRCABC.
https://circabc.europa.eu/d/a/workspace/SpacesStore/dce158e7-8c99-4886-aea7-a2a4771428ab/CA-March19-Doc.4.5%20-%20In%20situ.docx

It was not agreed at the March CA meeting, the next discussion expected at May CA meeting

Biocides assessment and CLH
The document "Biocides assessment and RAC opinion on harmonised classification (CLH)" was agreed at WG-V-2018.
The WG however requested endorsement by the BPC. Discussion took place at BPC-28 where changes were requested and it was agreed at BPC-29. In addition to the principles agreed by WG: If the eCA proposes (any) classification for genotoxicity, the RAC opinion on CLH needs to be available at the time of submitting the CAR
The document is in finalisation (with minor changes agreed at BPC-29) and it will be published.

Read-across framework (RAAF) – update
The report template is in finalisation. ECHA will ask interest for the training by email. Possibility for training/workshop (November 2019 to be confirmed): short introduction to RAAF concept, example cases e.g.

- Read-across assessment and reporting according to RAAF
- Example where read-across not approved as a result of the assessment

Some lessons learned:

- Early WG for new emission scenarios/non-standard exposure assessment (for Active Substances and Union Authorizations)
- WG members were invited to comment the minutes (add your proposed changes in track change modus - upload the revised version in the dedicated newsgroup)
- In case of questions related to WG membership/changes in membership or any other organisational questions concerning the WG meeting contact ECHA WG FMB
- ECHA suggested to provide the final versions of documents agreed at a WG/AHEE meeting one month after the meeting at the latest.

9.2 Active substance workshop: Feedback and actions

In February 2019, ECHA organised a workshop dedicated to the active substance approval process with a specific focus on the Review Programme. Representatives of MSCAs, ASOs and COM gathered together to have an open discussion on how to improve the active substance approval process, more specifically the evaluation and peer review phases, with a special focus on the Review Programme to unblock the current lack of submission of the draft CARs. Follow-up actions and proposal will be presented at the CA meeting in May 2019.

9.3 Update on EUSES

Concerning the EUSES quick fix/maintenance project: the Chair informed the WG that the official release of EUSES 2.2.0. has been postponed due to the ongoing ownership transfer of EUSES from JRC to ECHA. In the meantime ECHA will continue to add scenarios in the software that were recently agreed. The Beta-version of the software will be available for MSs and ASOs for testing and feedback. SECR recommended to try and test the software and to contact SECR in case of any possible issues.

Concerning the major EUSES update: the Chair informed the WG of the activities of the five ongoing TEGs. The presentation is available in **Appendix 3**.

DE asked all the MSs to share national data if available as regard suspended solids in sewer (TEG 3).

PT 8 Expert Group meeting (27 March 2019)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were EG members from the MS DE, NL, SE, DK, FR, FI, three participants from SECR and two members from EBPF/EWPM.

Participants were further 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.

2. Agreement of the agenda

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

3. Discussion of pre-identified items related to PT 8

The items for discussion were prioritised by the meeting participants and discussed in the order high, medium, low priority items. Some of the low priority items could due to time limitations not be discussed at the meeting, they will be followed up by a written procedure.

The conclusions on the discussed topics are provided in the following (items are provided in the order of discussion, not in the order of the DT):

<u>High priority items:</u>

1. Harmonised way to assess the read-across for different products regarding leaching *(FR, NL)*

The point remained open.

Conclusion: Some high level worst assumption for worst case product to be used for leaching test have been defined:

- Lowest binder content
- Non encapsulated
- No top coat versus top coated
- Water based versus emulsifiable
- Product with the highest AS concentration
- Product with highest application rate

Agreed Actions:

- **EBPF** will check if information/overview on binding effects of co-formulants are available: which co-formulants have the highest impact on binding properties of a product to the surface applied/leaching behaviour? Are lab leaching tests available to do such a comparison? Feedback to be provided to SECR.
- **EBPF** will identify active substances crating complexes with other actives substances and influencing the leaching behaviour and provide feedback to SECR.
- **SECR** to initiate e-consultation with EG members on specific questions raised by NL in their document (only EG members to be included, FR to provide in the frame the e-consultation an argumentation concerning the AF).

5. Leaching data from lab leaching studies for UC 4 (DE)

Point closed.

Conclusion: Leaching information on UC 4 can be used for UC 3 if no information is available and UC 4 test is seen as protective (e.g validate by comparing with other UC 3 leaching data performed with a comparable product). However the other way round is not possible since UC 4 leaching test results would represent the worst case. The exception would be for poorly soluble substances.

A correction for the retention needs to be performed.

Agreed actions:

- It was noted that guidance is missing on the interpretation of UC 4 leaching tests. Currently not sufficient information is available to prepare such guidance, more experience is needed. First step could be the comparison of different UC 4 leaching tests.
- **EBPF** to provide available information on UC 4 leaching tests to SECR.

8. Deriving endpoint from semi-field leaching studies (NL)

Point closed.

It was noted during the discussion that it is not in the remit of the EG to change relevant testing guidelines as such, however the following recommendation are provided which may make the outcome of the leaching test more reliable.

Conclusion:

1) It was recommendable to start leaching tests in autumn. The test should rather not start in the summer season. Since the starting date is not fixed in the leaching guideline, this can be only a recommendation.

   It was further recommended to put a clear statement of the drying time of the wood after application on the label. This drying time should then also be used in the frame of the semi field test to mimic a realistic situation.

   It was further recommended to compare the amount collected (i.e. the run off) with the actual rain amount, this may explain some inconsistencies in the leaching results (slight rain in combination with high evaporation does not lead to major run-off).

   It was discussed if a solution could be to start counting after the first rain event, there was no clear view.
2) It was recommended that the moisture content in the wood is measured (e.g. by two electrodes). It may explain deviations in the leaching tests but it was also seen rather as a nice to have than a need to have.
3) It was recommended to have more measure points at the beginning since it increases the statistical power. The first rain events have the highest impact.
4) It was recommended to run a semi field test at least two years. Reference was made to the guidance discussed at BAM in 2016, reflected in the leaching guidelines for PT 7, 10 where a test duration of two year are recommended (at least 5 test points in the first year and three in the second year). It is further recommended that the rain amount of two standard rain years is reached (i.e. 1400 mm).
5) Information on storage of leachate samples should be provided by applicants. It is recommended that known metabolites as well as known substances of concern should be covered in the analytic of the leachate (note that if no leaching data is available, default leaching rates will be used for metabolites in the risk assessment).
6) For very sorptive substances a proof of the recovery rate (e.g from the collection container where the substance may adsorb to) is further recommended.
7) During sample storage the container should be protected from sunlight and biotic degradation (e.g. by acidification of the container).

Agreed actions:

Concerning the 4), a follow up discuss on extrapolation of leaching test results for a longer time in case no plateau was reached was agreed for AHEE-3.

11. Interpretation of case specific leaching studies *(BE)*

Point closed.

Conclusion:

1) The EG agreed that the LoQ or LoD could be used (provided that the test results are reliable/reproducible). If the signal is between LoD and LoQ, the higher one (i.e. LoQ) should be used to calculate the leaching (as the value measured in the leachate).
2) No sampling points should be excluded, in the described case the LoD/LoQ should be used in the same way as described under 1) above.

The following further case specific feedback was provided: BE should check if the results are reliable, e.g. check if the issue could be the topcoat. Secondly check if any adsorption/degradation in the test vessel took place. Thirdly check if there are no experimental artefacts and if the analytical method is reliable.

Medium priority items:

2. Equations to calculate PEC in the different environmental compartments *(FR, DE)*

Point remained open. No conclusion was drawn since the document under preparation by NL (PvV) is not yet finalised.

Agreed actions:

- Final version of the document is under preparation by NL (PvV). **SECR** to forward the questions raised under this is item to PvV including the table document of EWPM in order to check if there are elements that would need to be taken into account. It was highlighted that it needs to be made clear in the document under which situation which equation should be used.
- Preparation of an excel sheet with the revised equations.
- **SECR** to check if new equations are already reflected in EUSES 2.2.0.
- **SECR** to check with NL if document should be scheduled for AHEE-3.

3. + 4. RMM at product authorisation level *(FR, DE)****/Definition of use class*** *(FR)*

Both points were closed.

Conclusion:

For UC 1 and 2 no risk assessment is performed. The EG agreed on the following RMM to be noted for professional and non-professional applications taking place outside of wood in UC 1 and 2 if there is no conclusion on UC 3:

"*During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpoline) and disposed of in a safe way*."

Concerning the questions if for industrial treated wood under UC 3 the RMM provided is acceptable, it was noted by IND that they have the legal obligation to label treated timber (as treated article) accordingly (pack labels for timber packs) if noted in the SPC:

"*The biocidal product may only be applied to timber which will not be used above or adjacent to surface water. The treated timber should be labeled accordingly*."

Agreed actions:

- **SECR** to forward the proposals for RMMs to the BPC for confirmation. In the case of the proposed instruction for use for UC 1 and 2, the question came up if it can be called RMM since no risk assessment as such is performed for UC 1 and 2.
- **DE** (Thorsten) to check if UC 4 can only be authorised if both, 4a and 4b are showing a safe use. For the time being there is no need to change the UCs in the ESD for PT 8, unless there is a strong request (by the WG) to revise the UCs in the ESD for PT 8.
- **SECR** to check with EFF WG chair which UC classification is use for efficacy.

Post EG meeting note: an e-consultation on the handling of use classes in other EU countries was initiated.

12. Follow up of AHEE – 2 AP 4.10 (NL)

Point closed.

Conclusion: SECR informed that the new Time 2 (365) is currently still under evaluation (impact study ongoing, SECR needs ERAs from eCAs to perform the impact study)

Action points (deadlines):

- **SECR** to remind eCA via the CG meeting that information on the ERA for PT 8 for Time 2 is needed for the impact assessment.
- **DE** and **NL** to follow up bilaterally and report back the outcome at AHEE-3 on the comparison of results from approach 1 and 2 (effect on extrapolation for persistent substances). However the previous AHEE conclusion is not foreseen to be changed at this point in time.

13. Case specific refinement of topcoated wood (FI)

Point closed.

Conclusion: The EG agreed on the proposed approach for a second tier to use the leaching data from the study period of the leaching test with topcoat without adding any AF and extrapolate the leaching data for the service life of the same product without topcoat, including the AF (2 or 5 depending on the duration of service life).

Low priority items:

6. Assessment of wood-preservatives for (long-term) prevention of anti-sapstain *(DE)*

Point closed.

Conclusion: The EG agreed that for general preventive treatment also against wood-discolouring fungi the existing OECD ESD scenarios for PT 8 should be used (and not the "Pallet scenario").

The remaining low priority items 7, 9 and 10 were not discussed at the meeting due to time constraints.

4. Closure and definition of follow up actions

The outcome of the PT 8 EG meeting will be presented at WG-III-2019 to the AHEE and ENV WG members for confirmation. Open items and items and low priority items not discussed at the meeting will be followed up via an e-consultation after the meeting.

Appendices:

Appendix 1: List of participants

Core members: (DE) Daniel **FREIN**
(FR) Stéphanie **ALEXANDRE**
(NL) Barry **MUIJS**
(UK) Melissa **REED – Alternate member**

Flexible members:
Maria a Marca (CH)
Anne Brasseur (BE)
Heulens Bart (BE)
Hadam Anna (PL)
Kantner Christian (AT)
Myriàm Martín Vallejo (ES)
Katja Michaelis (DE)
Schwanemann Torsten (DE)
Molnarova Jana (SK)
Muri Petra (SI)
Pasanen Jaana (FI)
Skou Cordua Birgitte (DK)
Wennermark Henrik (DK)
Sulg Helen (EE)
van Vlaardingen Peter (NL)

Rapporteurs :
Igaune Ieva (LV)
Lepage Anne (BE)
Benjamin Rat (FR)

ASOs:
Ossi **KASURINEN** (CEFIC Rep)

Appendix 2: Overview on guidance

Note:

- Guidance related items unchanged since WG-VII-2018 are highlighted in grey shading.
- Closed items are ~~stroke through~~.

1. Open guidance related documents

No.	Title (current leader)	Status
1.1	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[1] 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. SECR to inform also at CG on the ongoing collection of RAs and the impact assessment (action discussed and agreed at the PT 8 EG meeting).
1.2	Fish net scenario (**ECHA**): discussion on the usefulness of the new version of MAMPEC to be initiated	Discussion was started by NO. Possible inclusion in MAMPEC discussed with Deltares at AHEE-1, funding to be clarified by SECR (=> potentially in 2019). **On hold until EUSES projects are finalised.**
1.3	Guidance on aggregated exposure assessment (**DE**)	The discussion of the draft guidance is re-scheduled for an electronic procedure, to be started in Q1 2017. Documents were provided by DE to ECHA, SECR initiated e-consultation after the WG meeting. **Legal situation currently under evaluation by ECHA.**
1.4	TAB (**ECHA**): Technical Agreements on Biocides	**TAB database** under preparation following a request from WG members and CG (=> need to have assigned dates to TAB entries concerning the applicability for AS and BPs). Version numbers will be assigned to specific entries not to the TAB as such.
1.6	Development of guidance for bees and non-target arthropods ⇨ CG (2017)	Note: DE and CH have initiated national projects to collect information which could be the basis for a future guidance document. A further discussion on the need

[1] **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
		for guidance of bees triggered by several referrals discussed at the CG took will take place at WG-IV-2018. The conclusion was to focus first on RMM for bees and later develop the guidance. **E-consultation on the document presented at WG-IV-2018 took place in summer 2018.** **DE/CH have provided a revised document for discussion and agreement at WG-II-2019.**
1.7	Corrections of ESD PT 6 following discussions at WG-IV-2018 (**SECR**)	Agreed corrections will be implemented Q4 2018/Q1 2019. **Corrections have been implemented in the ESD, publication of revised version foreseen for April/May 2019. The corrections are also implemented in EUSES 2.2.0.**
1.8	Invasive exotic mosquito control with adulticides (**NL**)	AHEE consultation initiated by NL (deadline: 7. September 2018). Discussion at AHEE-2, NL will continue with their proposal and follow up on some of the pending actions **Agreed actions at AHEE-2:** - Some members (DE, CH) to consult PPP experts for items interception, bees and NTA. CH has now provided some feedback from their national situation. - ECHA and NL to collect any relevant information from other MS that were not present during AHEE. Information on whether there is control of invasive mosquitoes, specifically using adulticides and any information on current practice is welcome. - ECHA has advised NL to make a consultation at the CG through their CG representative to collect feedback from other MS. **Follow up ongoing, CH provided feedback on 18 March 2019.**

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

No.	Title (current leader)	Status
ASSIGEND ITEMS		

No.	Title (current leader)	Status
2.1	PT 3: Scenario for disinfection in aquaculture (**ECHA**) ⇨ *Disinfection project/EMA visit*	ECHA contracted out the preparation of a first proposal. First discussion took place at WG-I-2017, comments received during the commenting period to be added. **Preparation of revised version currently on hold due to other priorities.**
2.2	Clarification on DT50 values according to the FOCUS guidance to be used for modelling purpose and as trigger value (for higher tier studies/PBT assessment) ⇨ *WG-I-2016 – item 6.3b*	**DE/UK** volunteered to take over the item (update of PBT guidance to be taken into account). Timing to be defined.
2.3	PT 11: Which fraction should be used to calculate the PEC in soil following deposition from air? ⇨ *WG-IV-2016 – item 6.3*	NL prepared a document for AHEE-2 which explains and evaluates the currently available methods to calculate PEC_{soil} in PT 11 scenario's following the ESD for PT 11 and the implementation in EUSES and proposes a working procedure and recommendations for improvements. The document did not contain any new methods/calculations. It was agreed at AHEE-2 to follow up the item via an e-consultation. SECR initiated the e-consultation among the AHEE members. **NL to revise the document after the e-consultation. SECR to re-table the document either in a dedicated WebEx meeting or at the next AHEE meeting.**
2.4	PT 4: Is splitting up the release from on-site/off-site STP in the case of large breweries relevant and is the proposed percentage (on-site = 33% / off-site = 67%) realistic? ⇨ *WG-V-2016 – item 6.1*	**NL** volunteered to take over the item. Timing to be defined.
2.5	Derivation of a default value for Felim for certain type of substances (**NL**) ⇨ *WG-I-2018 – item 7.6*	In the discussion at **AHEE-2** it was agreed to use the general default F_{elim} value of 0.7 in PT 4 applications with on-site treatment, for substances with a K_{ow} of ≥10000 (to be applied as a potential refinement for all scenarios in PT 4, beside if specifically breweries are considered or the disinfection of wine barrels since fat separators are not relevant in these cases). The WG agreed to keep a default value of 0.9 for F_{elim} for rapidly reacting substances like e.g. oxidizing substances. Concerning the risk mitigation measure 'a grease separator it was agreed that a restriction to a surface of above 2000 m^2 is not needed since in several member states fat separators are also in place in small kitchens/restaurants.

No.	Title (current leader)	Status
		NL finalised the document taking into account the above conclusion and provided it to SECR. **SECR to publish the document on the public CIRCA side.**
2.6	Direct emission to surface water – Definition of Tier 2 (**NL**) ⇨ *WG-II-2018 – item 7.2*	NL will start mapping place of direct release to surface water as preparatory work for a Tier 2 preparation. AHEE-2: Concerning RMMs, concerns were raised that they are only applicable to certain product types. Stability studies were considered as not helpful since there is no information on the time after application and final use of the product. It was further proposed to look at real data, i.e. concentration of substances measured in surface water in order to validate the model. SECR raised concerns that if no refinement for the scenario are in place, no substance will pass the risk assessment. **No conclusion was drawn at AHEE-2 SECR to get in contact with M. Burkhard concerning COMLEAM (M. Burkhard will be invited to provide a presentation on COMLEAM at the PT 8 EG meeting).**
2.7	PECsediment – direct release to surface water (**NL**) ⇨ *WG-II-2018 – item 7.3c*	First discussion at WG-II-2018, agreement that NL should provide worked examples at AHEE-2. NL presented a document at AHEE-2 which provides example calculations on how to calculate $PEC_{sediment}$ from a static pond-water system and provided background information for the discussion. During the discussion, the following issues were raised: - The possibility of including in the document the strategy on how to apply the equations - Whether sedimentations has been taken into account in the calculations - The need to clarify when to apply these calculations to static water. The AHEE agreed to follow up this item via an e-consultation which was initiated by SECR. **Follow up to be discussed with NL.**
2.8	PEC calculation service life sediment – direct release to surface water (**NL**) ⇨ *WG-II-2018 – item 7.3g* ⇨ *WG-IV-2018 – item 6.3*	Discussion at WG-II-2018, procedure with regard to PEC_{TWA} agreed, approaches for leaching calculation discussed at WG-IV-2018, still open. AHEE-2: NL presented a document that summarises the differences between two approaches to calculate the concentration at the end of the emission period **Follow up of the item at the PT 8 EG meeting.**
2.9	Simplification of exposure assessment ⇨ *WG-II-2018 – item 7.5*	In the frame of the EUSES quick fix project, core scenarios have been identified which will presented together with assessment of MS on worst case scenarios at **AHEE-2**.

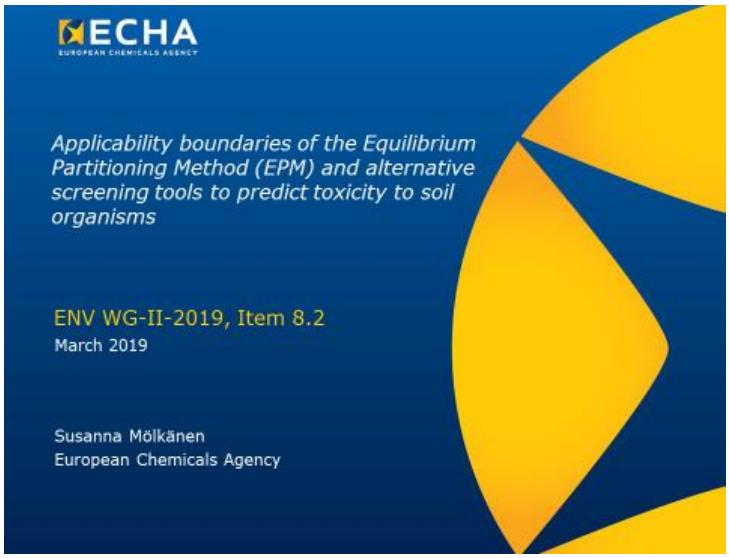
No.	Title (current leader)	Status
		SECR is currently working on the validation of cores scenario 2. It will be presented at the next AHEE (or TEG-1) meeting.
2.10	Refinement options for PT 11 once through and large recirculating systems ⇨ *WG-II-2016 – item 6.8/6.9*	FR presented a document at **AHEE-2**: The AHEE agreed: • that STP connection should be only considered for small recirculating cooling systems. • that the pond can be an acceptable RMM, however it would need to be verified case by case if this RMM is acceptable for the specific substance. **FR presented a scenario; FR will revise the equation and input parameters based on the comments received and the revised scenario will be agreed in a written procedure.**
2.11	PT 6: Development of an emission scenario for the preservation of unrefined fuels (**NL**) ⇨ *WG-V-2015 – item 7.3, WG-II-2018 – item 7.3d*	**E-consultation initiated on agreed changes: deadline for providing your feedback is 1 April 2019.**
2.12	PT 18: Use of treated water for irrigation of private gardens - exposure estimation of soil compartment **(DE)** ⇨ *AHEE-2*	Discussed and agreed at AHEE-2, DE provided the final document. SECR to publish on the public CRICA side. Note of DE: we have to make you aware that we have not only incorporated the discussion results of AHEE-2, but also revised the definition of DT50 water (DT50 hydrolysis instead of DT50 biodegradation in surface water). The possibility of consideration of hydrolysis as degradation process in the emission scenario was not discussed at AHEE-2, thus in our opinion the MS should be at least informed about this amendment before publishing the document on CIRCA side. **SECR will initiate a brief written procedure for the AHEE if the change proposed by DE is acceptable.**
2.13	Exposure assessment of metabolites in the terrestrial compartment - indirect exposure via manure/slurry application on agricultural land **(DE)** ⇨ *AHEE-2*	Discussed and agreed at AHEE-2, DE provided the final document. SECR to publish on the public CRICA side.
2.14	Two documents provided by DE for AHEE-2: • Disinfection of drip irrigation water (PT 2) • Negligible environmental exposure due to the	The final documents have been provided by DE. SECR to publish on the open CIRCA side.

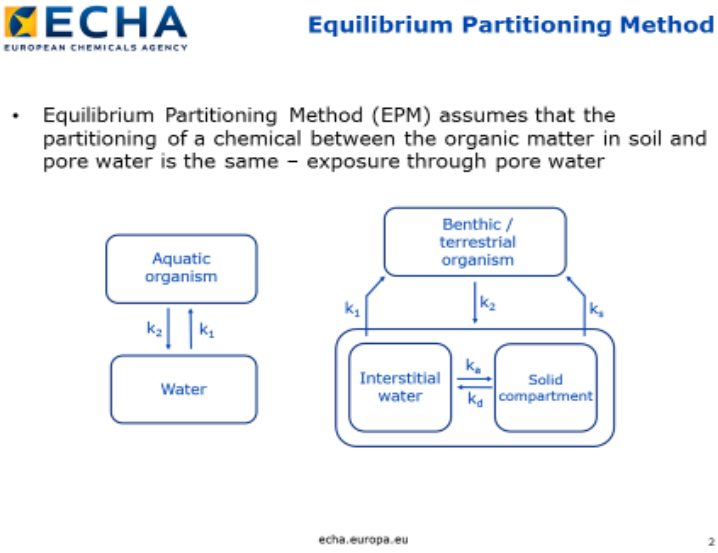
No.	Title (current leader)	Status
	disinfection of surfaces with RTU wipes in PT 2 and PT 4	
OPEN ITEMS (priority indicated in colours: high = red, yellow = medium, green = low; prioritisation based on the time lines provided in Annex III of the RPR)		
2.15	PT 18: How to derive values for the cleaning efficiency FCE (=> Release and exposure estimation of the biocidal product during cleaning step) ⇨ *WG-III-2015 – item 6.4*	AHEE member to take over item to be assigned.
2.16	Development of RTU/small scale application scenario for PT 18 (household and professional use) ⇨ *WG-II-2016 – item 6.2*	AHEE member to take over item to be assigned.
2.17	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.
2.18	PT 21: AHEE consultation - consideration of the PT8 ESD for accumulation and degradation processes (equation 3.11), and the emission pattern for soil exposure (batch-wise vs. continuous release). ⇨ *WG-III-2016 – item 6.4 (AHF)*	SECR to initiate.
2.19	PT 19: review of default value for Fsim (worst case to apply the Fsim of PT 18 to PT 19?) ⇨ *BPC-19 – AP 07.05*	AHEE member to take over item to be assigned.
2.20	Focus SWASH: Use of the model for calculation of PEC in sediment (PT 3, run-off from soil) ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.21	PT 7: Revision of the ESD (inclusion of the formulation step, alignment of equations with A/B tables) ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.22	PT 9: Definition/revision of fixation factors for PT 9 – leather applications ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.

No.	Title (current leader)	Status
2.23	PT 9: Concentration in soil in PT 9 rubber-roof membrane scenario ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.

Appendix 3 - Presentations

3.1 Outcome of EPM project





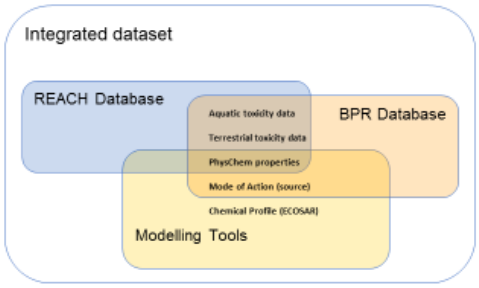
Aim and Partners

- Investigate the applicability boundaries of EPM within a regulatory context (REACH and Biocides)
- Assess if the screening approach is sufficiently protective of the soil compartment as currently applied under REACH and BPR
- Identify ways to improve the reliability of EPM and consider value of alternative approaches
- Project launched September 2016, data set and analysis updated Q4 2018
- Partners: ECHA, ECETOC, Concawe and Environment and Climate Change Canada (ECCC)

Equilibrium Partitioning Method in Regulatory Frameworks

- Under REACH and BPR
  - Used primarily as a screening method for terrestrial compartment
  - Often used to compensate for lack of terrestrial data
  - Under REACH to assess hazard to soil organisms in absence of data according to soil hazard categories I-IV
  - Under BPR when tests on soil or sediment not required, when available test results not reliable or when data is limited
- Motivation for the project to gain an insight into how EPM is used as EPM is often misused or used in absence of terrestrial data

Data Sources



Several data sources were used to compile an integrated data set. Limited to ECHA regulatory data, does not include literature data.

Selection Criteria

- Reliable information on aquatic toxicity
  - i.e. test not performed over limit of water solubility, analytical monitoring, effects estimated on mean measured concentrations
- At least one terrestrial study (invertebrates or terrestrial plants)
- Reliable experimental values for VP, WS, and K_{OW}
- Reliable data on environmental fate characteristics
- Experimental studies on adsorption/desorption (preferably batch equilibrium on several soil types i.e. OECD 106)

Description of the Data Set

- 38 substances; (15) REACH and (23) BPR substances
- Mostly organic monoconstituents and few well-defined multiconsituents
- log K_{OC}: 1.49 – 6.04 (12 log K_{OC} > 4)
- log K_{OW}: -1.48 – 7.00
- WS: 0.002 mg/L – 500 g/L
- VP < 5 Pa
- 23 ECOSAR classes

Table 2. List of ECOSAR classes the substances belong to.

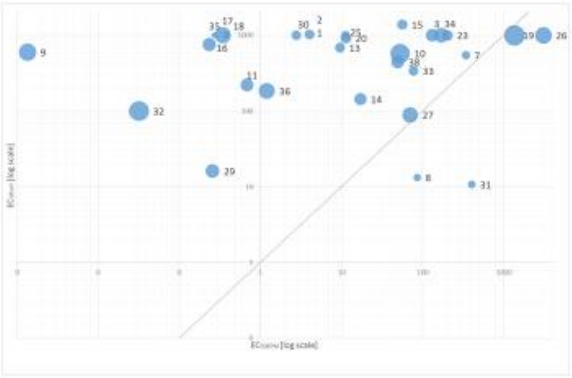
Aliphatic Amines	Thiazolones (Iso-); Vinyl/Allyl Halides	Substituted Ureas
Triazines, aromatic	Triazoles (Non-fused)	Neutral organics, Aliphatic Amines
Esters; Phenols	Benzodioxoles	Anilines
Phenols	Carbonyl Ureas	Pyrazoles/pyrroles
Imidazoles	Vinyl/Allyl Halides; Propargyl Halide	Neonicotinoids
Esters; Esters (phosphate)*	Phenols, poly	Melamines
Aliphatic Amines; Nicotinoids	Esters	Halopyridines
Pyrethroids; Esters; Vinyl/Allyl Halides; Benzyl Nitriles	Neutral organics	Not related to an existing ECOSAR class definition (unclassified)

*ALERT: potential surfactant properties

Comparison of Effect Values from Aquatic and Terrestrial Invertebrate Studies

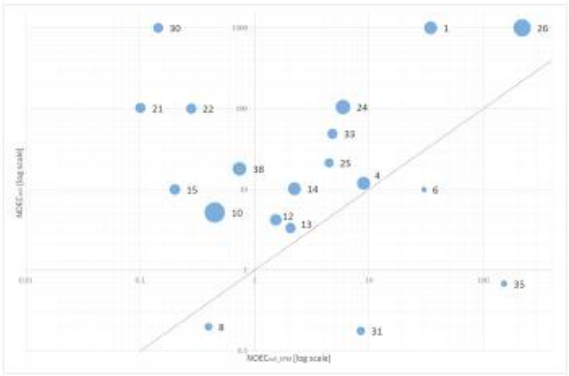
- EPM applied to acute (EC_x) and chronic (NOEC) invertebrate data
  - Eliminate influence of AFs
  - Allow comparison between aquatic and terrestrial invertebrates (as opposed to most sensitive organisms) – *not typical application of EPM*
- Log linear correlation between EPM predicted vs. experimental
  - $EC50_{soil}$ vs. $EC50_{EPM}$
  - $NOEC_{soil}$ vs. $NOEC_{EPM}$
- Allows visualization of where the substances lie in relation to a bisect (y=x where EPM prediction=experimental)
- Determines where EPM may underestimate toxicity

Invertebrate EC_x Prediction



29 substances with acute invertebrate EC_{50} data (mostly from *Daphnia* and Earthworm)

Invertebrate NOEC Prediction

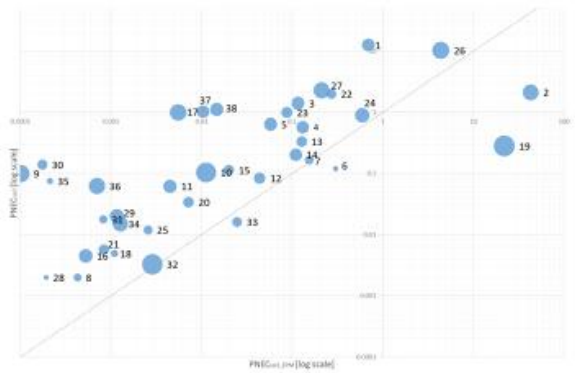


19 substances with chronic invertebrate NOEC data (mostly from *Daphnia* and Earthworm)

Comparison of PNEC and Physico-chemical Properties

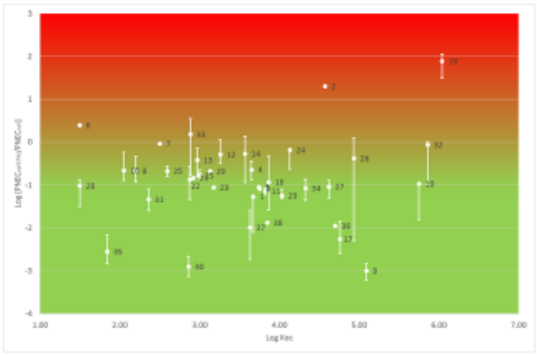
- Log linear correlation between EPM predicted vs. experimental
- Further correlation with Log[$PNEC_{soilEPM}/PNEC_{soil}$] vs. K_{OW} and K_{OC}
  - For K_{OC} an additional analysis into the possible range of results from range of K_{OC}
- Determined from effect values of most sensitive organisms from aquatic and terrestrial toxicity data
  - For all 38 substances; invertebrates most sensitive for 22 aquatic and 18 terrestrial
- AF used were in line with regulatory data (i.e. data available)
- Insight into influence of physico-chemical properties

Invertebrate $PNEC_{soil}$ Prediction



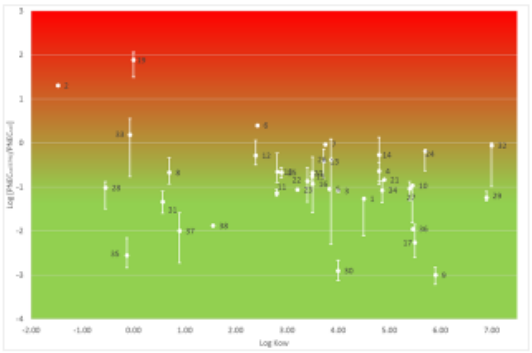
Better "fit" of data between predicted ($PNEC_{EPM}$) and experimental ($PNEC_{soil}$)

$Log[PNEC_{soilEPM}/PNEC_{soil}]$ in Relation to K_{OC}



- Toxicity underestimations (6, 8, 19, 26, 31, 35) seen in EC_{50} and NOEC
- Only 2 (Aminoethyl piperazine) and 19 (DDAC) underestimated by a magnitude > 1
- Highlights importance of K_{OC} selection especially for substances with a wide range

$Log[PNEC_{soilEPM}/PNEC_{soil}]$ in Relation to K_{OW}



- K_{OC} may be estimated from K_{OW} for substances
- Regulatory trigger value of log K_{OW} > 5 for terrestrial testing

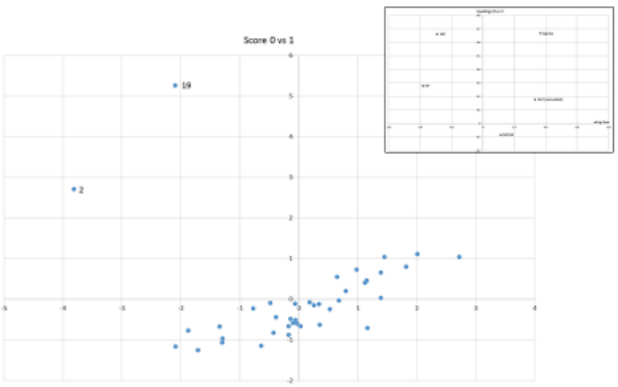
PNEC Prediction and Physico-chemical Comparison

- AF influences EPM estimation
- Two substances may be outliers in data (2, 19)
  - Further investigation with PCA if underlying influence of physico-chemical properties
  - a result of K_{OC} estimation (i.e. read-across for 2)
  - Substance properties not applicable for EPM estimation (i.e. DDAC as an ionisable substance)

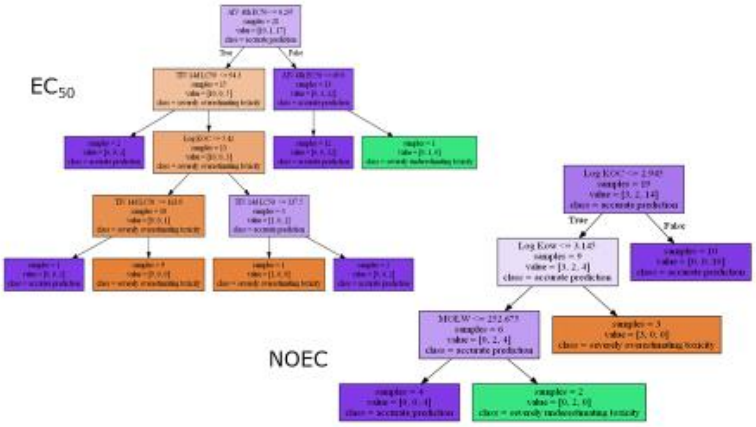
Further Analysis

- Statistical analysis with single factor ANOVA and two-sample t-Test
  - EPM results from EC_x may not be comparable to NOEC and PNEC analysis
- Principal Component Analysis
  - Examine influence of physico-chemical properties (Mw, VP, WS, log K_{OW} log K_{OC}, HLC) if explained differences or highlighted outliers (2, 19) in the data set
  - Same outliers identified as from PNEC analysis (Aminoethyl piperazine and DDAC) potential influence of their VP, WS
- Decision Tree
  - Visualise possible influence of physico-chemical properties and effect values in EPM estimation
  - Acute and chronic data
  - Limited analysis due to availability of acute and chronic data as well as size of the data set

Principle Component Analysis



Decision Tree



Alternative Screening Approaches

ECCC approach case studies;

- Critical body residue (CBR)
  - Concentration of chemical in organism, corresponds to defined measure of toxicity
  - Useful for very hydrophobic substances as well as organic narcotics
  - Less variable among species and environmental conditions, however, not established for most reactive toxicants or metals
- Chemical activity
  - Measure of chemical reactivity
  - Activity useful for identifying specially acting chemicals that are outside the boundaries of EPM (i.e. interspecies variability is high)
- Critical membrane toxicant concentration (CMC)
  - Toxicity for chemicals with high membrane-water partitioning (K_{mw}) i.e. aliphatic amines or other cationic species

Conclusions

- Data supports the current regulatory approach
  - Where to apply, where care should be taken
- Results of project are generally consistent with other literature studies with EPM
- Highlights the importance of good quality data, especially for aquatic toxicity and physico-chemical properties i.e. K_{OC}
- Consider soil types in K_{OC} derivation; range if available or selection of soil type i.e. sandy loam
- Substances with aquatic and terrestrial range of studies is limited (e.g. specific substances i.e. sorptive substances not always possible to conduct aquatic studies)
- Acknowledging the potential for alternative methods
  - e.g. CBR for hydrophobic substances, CMC for aliphatic amines, both for narcotics.

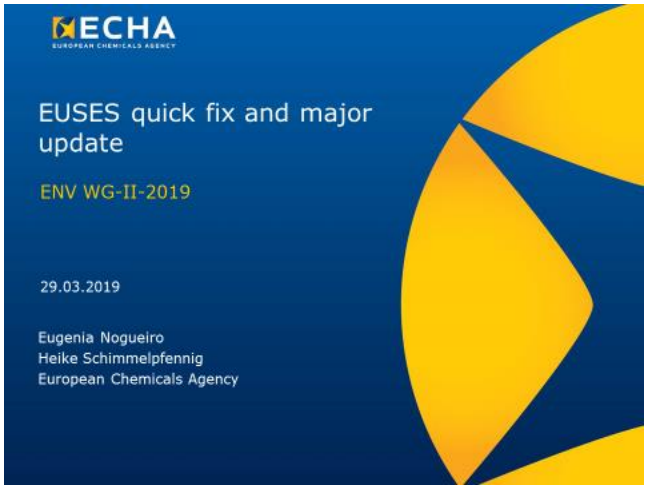
Potential areas for further research

- Applicability of EPM for substances with a specific MoA
- Invertebrates were the many focus of the analysis, expand to other groups of organisms
- Similar analysis on sediment studies
- Further work on alternatives for K_{OC} (e.g. K_{cec})

Next Steps

- SETAC presentation "Applicability boundaries of the Equilibrium Partitioning Method (EPM) and alternative screening tools to predict toxicity to soil organisms" on Wednesday, May 29th.
- Disseminate and publish report (+ public dataset) to ECHA website

3.2 Update on EUSES



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EUSES quick fix

- EUSES 2.2.0 ready but waiting for legal issues to be clarified → release postponed
- In the meantime implementation continues:
  - PT 2 – Treatment against algae
  - PT 4 – Disinfectants used in food and feed areas
  - PT 9 – Preservation of shoes in shoeboxes
  - PT 14 – new ESD (except secondary poisoning)
  - Bug fixing
- Beta-version will be shared with MSs and ASOs for testing in Q2 – we will inform by email

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5 Technical Expert Groups (TEGs)

1. Release scenarios (overall approach) (topics 2, 3 and 5)
2. Release to agricultural soil (topic 4)
3. Degradation in sewer + Simpletreat (topics 6 and 7)
4. Metals topics (topics 14, 15, 18, 22 and 24)
5. EUSES/Chesar user experience: to provide feedback on proposals by contractor for EUSES as a standalone tool or EUSES within Chesar

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TEG 1 - "release scenarios"

Release estimation

- Direct release route
- Release rate (kg/day)
- Additional criteria?
  - Repeated application/ Continuous release…

Fate and distribution model

- Local exposure (in receiving compartment and subsequently exposed compartments)
- Regional exposure

"Release scenario" provides information for the release estimation + selection of fate and distribution model

TEG 1 - status

- First WebEx took place 14 February
- Background document shared 12 March
  - Progress on analysis of fate models, grouping still to be done
- Feedback deadline 3 April

- In the meantime work continues
  - Core scenarios
  - Analysis and grouping of fate models
  - Initial design for release module

- Next steps to be decided based on feedback received from TEG and on results of further work

Release estimation

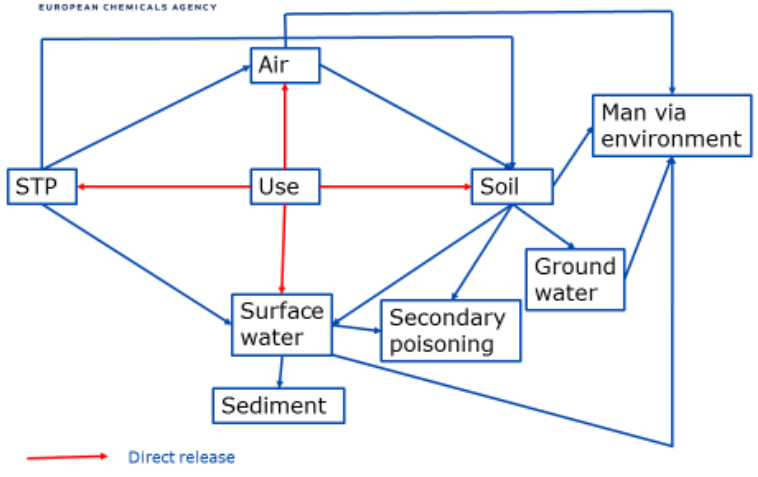
Release rate (kg/day) =
Amount available for release (A) * Release Factor (RF_{route})

- Based on use tonnage and
  - Defaults in R.16 (REACH)
  - Defaults in B-tables (Biocides)
- Site-specific information
- "Consumption-based"
- Msafe?

Core scenarios

- Defaults
  - ERC (REACH)
  - A-tables (Biocides)
- "Consumption-based" ESDs (Biocides)
- SpERCs (REACH)
- Other sources (e.g. OECD ESDs)

Alternative: Measured release (M)



Proposed approach

- "Unified module" covers REACH and biocides
  - All possible ways to calculate release rate (including core "consumption-based" scenarios)
  - All possible compartments (directly) released to, with harmonised distribution/fate models
- Guide user in selecting the relevant entries and pre-fill with defaults, with possibility to modify (incl. justification)
  - If standard REACH scenario is selected, release estimation based on default tonnages and ERC release fractions, and release to STP and air selected
  - If Biocides PT is selected, then release estimation method as well as routes released to and default parameters are automatically filled based on ESD

TEG 2 – timeline

- WebEx meetings took place on 17 January and 6 February
- Background document circulated and commented, discussions took place on
  - Current approaches
  - Differences between the approaches
  - How to move forward to establish one common scenario
- Face to face meeting will took place 27 March

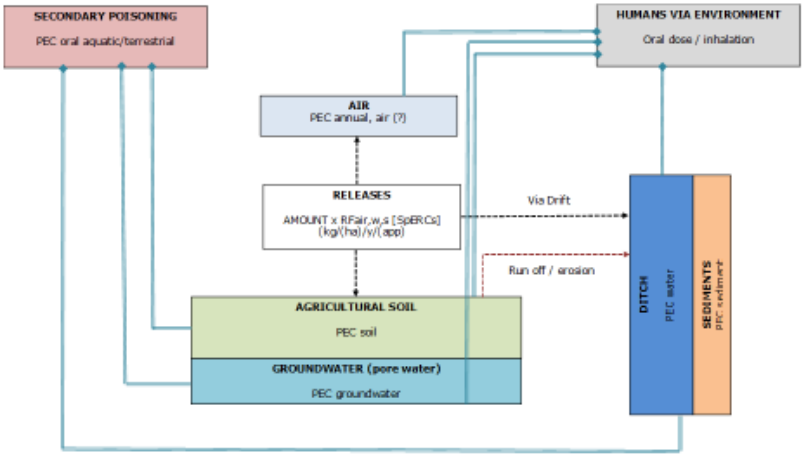
TEG 2 – outcome so far

- Similar views on many of the open questions:
  - **Conceptual model**: agreement on ditch surrounding agricultural field (Tier I under FOCUS); parametrisation is needed (might be different than river)
  - **Conceptual model**: decision on having separate scenario for direct releases and not updating EUSES standard (sludge)
  - **Secondary poisoning**: agree to have it in the scenario; PECwater used in secondary poisoning for fish concentration to be averaged over <30 days (not 365 days)
  - **MvE**: agreement on having it for the default assessment; for PEC air we need to: a) identify suitable model to estimate it after emission; b) agree on averaging time (e.g. 30 days).
  - **Releases and OC/RMM**: single (default) and multiple applications to be allowed in EUSES; no OC/RMM

TEG 2 – outcome so far

- (continued):
  - **Soil model**: common views for 10 years of application. Equations are same as currently in EUSES. PECsoil (30 days averaged) to be calculated for 5 cm and 20 cm of soil depth; PECsoil (180 days averaged) calculated for MvE and secondary poisoning; PEC initial for 5 cm as well?
  - **Indirect releases to water**: run off (and erosion) calculated as in FEE tool (equation available)? Or as fixed percentage of applied substance?
  - **Water/sediment compartment**: different models used; discussion needed on what is the best for EUSES; averaged concentration (including biodegradation) vs max concentration after application.
  - **Other issues**: tools comparison (still limited)

Conceptual model



TEG 3 timelines

- 1st teleconference 4/2/2019 where initial document was discussed and first reflections were gathered
- Feedback provided by 25/2/2019
- 2nd teleconference 20/3/2019
- *3rd teleconference in 1st half of May*

Outcome of 2nd teleconference (1)

SimpleTreat:

- ECETOC will provide further statistical analysis of data as well as (possibly) add information on more countries in support of the changed concentration of suspended solids, which will be evaluated by the TEG
- Koc QSARs for ionising substances used in SimpleTreat 4 while Koc QSARs were agreed to be removed from EUSES in line with the decision of the June 2018 Workshop, further analysis to be undertaken by ECHA and RIVM on practical implications

Outcome of 2nd teleconference (2)

SimpleTreat:

- IND STP mode was agreed to be available as an alternative to municipal STP mode. If serial connection is foreseen that would be possible to model only by assuming RMM (on site STP) followed by municipal STP
- Monod kinetics was decided to be reincluded
- Need for guidance was identified with regard to
  - use of industrial STP mode of SimpleTreat 4
  - non-correction of biodegradation rates from ready biodegradability tests
  - how to derive Koc for ionising substances

Outcome of 2nd teleconference (3)

Degradation in sewer

- A sewer degradation model with the exponential decay equation was agreed to be added to model abiotic degradation following biocides practice
- It was agreed to leave the possibility to registrants/ applicants to use it also if biodegradation in sewer is considered relevant
- Sewer would be modelled as a form of reduction of the initial amount available for release to wastewater (≠compartment) i.e. would be available regardless of whether wastewater is treated or not

Outcome of 2nd teleconference (4)

Degradation in sewer

- ECETOC agreed to provide some additional calculations to demonstrate the impact of the biodegradation in sewer on the STP effluent concentration which will be later reviewed by TEG
- Allowing parallel assessment of metabolites/degradation/ reaction products generated in sewer was supported
- TEG reminded of the need to perform the parallel assessment of the metabolites generated in STP as well
- A need for clarification of different sewer options with regard to rainwater discharge and connection to STP was identified before it can be discussed in which cases sewer degradation is relevant or not (biocides)

Scope of activities

metal fate	• **Topic 22: Account for metal fate (immobilization) processes** • Topic 14: Different Kp(sup) and Kp(sed) for seawater and freshwater
MvE	• **Topic 17: Man indirectly exposed via the environment** • **Topic 18: Man via the environment for inorganics: alternative model for crop exposure pathway**
Regio-nal /local	• Topic 15: Use PECregional sediment in PEClocal sediment calculation • Topic 24: Consideration of natural background concentrations for inorganics

Ongoing activities

- Develop time horizon document based on RAR Zn, Cd, Ni (from EU ESR programme)
- Evaluate concept of metal "immobilization" first order rate
- Further investigation of aerial metal deposition to crops and subsequent uptake
- Impact on PECsediment when PECsed/regional is calculated either via EPM from PECwater or by SimpleBox separately

TEG 5 "EUSES/Chesar"

- Kick-off took place 21 March
- Presentation of delivery options
  - EUSES and Chesar independent
  - EUSES in Chesar
  - EUSES and Chesar "bundled together"
- Presentation of the way these options will be assessed/compared, asking for input on which criteria were considered most important
- Feedback requested by 12 April
- Next steps to be determined after feedback received and further progress made

Next steps

- TEGs continue
- 4th WS ECHA – Contractor (May)
- Call with interested authorities (May/June) – if you would like to be included let us know!
- Next SC WebEx? First half of May?

Human Health WG-II-2019

Final minutes

23 May 2019

Minutes of Human Health WG-II-2019

26-28 March 2019

Meeting of the Human Health Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 28 members registered, of which 6 were core members. One stakeholder representative was present. Applicants were registered for their specific substance and Union authorisation 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 informed that:

- One UA case is currently foreseen for PF 32 (July WG);
- A new collaboration tool – InterAct – is expected to replace S-CIRCABC in 2020;
- A reorganisation took place in ECHA. The Biocides unit was split into 2 units : Biocidal Active Substances (D1) and Biocidal Products (D2);
- WG members should inform SECR when leaving the MSCA.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. 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 draft minutes from WG-VII-2018

The minutes were agreed without further changes.

6. Discussion of Union authorisation applications

Closed session

A closed session took place to discuss the principles of identifying substances of concern (SoC) and using national and EU OELs for identifying SoCs. According to current guidance, OELs need to be considered in identifying SoCs, but the OELs are not necessarily health-based. The members noted that identifying and interpreting national OELs might be challenging, and that the Guidance on SoCs might need to be revised. Nevertheless, some members considered information on OEL values valuable and asked these to be included in PARs. The need for further discussions and guidance was flagged.

6.1 UA for product family containing Hydrogen peroxide PT 01-04 (eCA LV)

Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

6.2 UA for product family containing Octanoic acid/Decanoic acid PT 04 (eCA BE)

Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

6.3 UA for product family containing Octanoic acid PT 04 (eCA NL)

Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

6.4 UA for product family Permethrin/S-Methoprene PT 18 (eCA FR)

Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

7. Discussion of active substances

7.1 DBNPA ED assessment (eCA DK)

Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

7.2 Sulfur dioxide generated from sulfur by combustion PT 04 (eCA DE) and 7.3 Sulfur dioxide released from sodium metabisulfite PT 09 (eCA DE)

Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

8. Technical and guidance related issues

8.1 Update on guidance development

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

8.2 HEAdhoc: PT 18 professional exposure scenarios

DE presented a proposal for including PT 18 professional exposure scenarios as part of HEAdhoc Recommendation 6, version 4. The WG members supported the proposal and the inclusion of the exposure calculations as an Appendix to the Recommendation. It was suggested to include a link to Recommendation 3 on spraying for assessing exposure to insecticides for low pressure downward uses. The WG agreed on the proposal.

8.3 Dermal absorption of a repellent used together with sunscreen/sun lotion products

SE presented the document. It was proposed to use the RMM phrase only for DEET products, since there is no further literature on other repellents available. The wording of the risk phrase was discussed in more detail and the WG agreed on 'When used in combination with sunscreen, always apply the repellent after the sunscreen has dried'.

SE proposed to identify an appropriate, possibly fixed assessment factor to estimate the dermal absorption when repellents are used together with sunscreens. For this, additional literature search would be needed but none of the members volunteered.

8.4 Harmonising the use of default dermal absorption values derived according to EFSA (2017)

An e-consultation took place on the DE proposal to clarify the interpretation of the EFSA Guidance on dermal absorption (2017) by defining concentrates and dilutions as agreed in SANTE/2018/10591 rev.1. When using the EFSA guidance, a biocidal product should be considered:

1. A "concentrate" when the active substance is present in the biocidal product at a concentration higher than 50 g/L (or 50 g/kg or 5%);
2. A "dilution" when the active substance is present in the biocidal product at a concentration lower than or equal to 50 g/L (or 50 g/kg or 5%).

The members supported the DE proposal and SECR proposed including it as an entry in the TAB. The proposed TAB entry was agreed by the HH WG.

8.5 Updating the WG recommendation for in situ generated active substances and their precursors

SECR gave an update on the revision of the WG recommendation for in situ generated active substances and explained the outcome of the gap analysis in the HH section. Some additional needs for further guidance were identified by the members:

- How to determine the relevance of by-products;
- How to set reference values for precursors and disinfection by-products;
- free radicals;
- If testing is not possible, how to deal with the exposure and risk assessment;
- How to deal with metals that generate free radicals in matrix.

SECR asked the members and ASOs to provide further input directly to SECR, clarifying that contributions would be appreciated with proposed solutions and not with further gap analysis.

8.6 Read-across for biocides

The Read Across Assessment Framework (RAAF) was presented to the members of the WG. The presentation included the principles of RAAF along with an example of application of RAAF in read across evaluation of biocidal active substances and a proposal of RAAF implementation in biocides risk assessment. ECHA will open an e-consultation to request the views on whether to implement RAAF in read across evaluation in biocides.

9. Any other business

9.1 Other information & lessons learned

The presentation is available in S-CIRCABC to MSCAs and to associated stakeholder organisations.

Dermal absorption of rodenticides

DE informed on the work performed following WG-VII-2018, where the DE member volunteered to prepare a document on dermal absorption values for anticoagulant rodenticides and the FR member volunteered to provide support. The document is currently under commenting in DE and will subsequently be shared with FR for review.

Endocrine disruption (ED)

SECR informed that three ED Expert Group (EG) meetings are scheduled for 2019. The provisional dates are:

- 4-6 June
- 1-3 October
- 3-5 December

The deadline for confirming the substances for the June ED EG is 9 April 2019. SECR asked the members to confirm the substances by sending an e-mail to ed_eg@echa.europa.eu.

SECR informed that the UK document *Assessment of ED properties of co-formulants in biocidal products – draft instructions for applicants* was agreed at CG-34 (12-13 March 2019) with minor changes, but the final document is not yet available. Another document providing instructions for MSCAs will be prepared by FR. An e-consultation in CG is expected to be launched in April 2019.

Biocides assessment and CLH

SECR informed that the document *Biocides assessment and RAC opinion on harmonised classification (CLH)* which was agreed at WG-V-2018 was discussed and agreed at BPC-29. In addition to the principles agreed by the WG, if the eCA proposes (any) classification for genotoxicity, the RAC opinion on CLH needs to be available at the time of submitting the CAR. The document will be finalised with minor changes agreed at BPC and published.

PAR template

At the last CG meeting, it was agreed to revise the PAR template. SECR informed that it intended to submit a proposal for the HH section. Members are invited to liaise with their CG representatives.

Next WG meetings

SECR informed of the provisional timing of the next Human Health WG meetings:

- 21-22 May[1]
- 8-10 July (exact days to be established)

9.2 Active substance workshop: Feedback and actions

In February 2019, ECHA organised a workshop dedicated to the active substance approval process with a specific focus on the Review Programme. Representatives of MSCAs, ASOs and COM gathered together to have an open discussion on how to improve the active substance approval process, more specifically the evaluation and peer review phases, with a special focus on the Review Programme to unblock the current lack of submission of the draft CARs. Follow-up actions and proposal will be presented at the CA meeting in May 2019.

[1] These are the confirmed dates. This is slightly different from the information provided at the meeting where 22-23 May was considered.

Annex 1

Human Health WG attendees

Core members
MIKOLAS Jan (CZ)
HOLTHENRICH Dagmar (DE)
ZIKOVA Andrea (DE)
HERRMANN Kristin (DE) - alternate
ARAPAKI Niki (EL)
LAUMONIER-MAXIMILIEN Elisabeth (FR)
LORI Julia (FR)
WELTEN Angelique (NL) - alternate
Rapporteurs
LEPAGE Anne (BE)
JENSEN Stine (DK)
RAT Benjamin (FR)
KADIKIS Normunds (LV)
Flexible members
HAUZENBERGER Ingrid (AT)
HERREMANS Yannick (BE)
BRYS Kristel (BE)
DOLEZELOVA Katsiaryna (CZ)
GEBEL Thomas (DE)
KÄOSAAR Sandra (EE)
HYVARINEN Tuija (FI)
VÄLIMÄKI Elina (FI)
LESER Vladka (SI)
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