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

(Meeting date: 28 May 2019)

17 September 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.

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:

- Post-approval information: Analytical methods for active chlorine releaser.
- Hydrogen peroxide radicals generated from hydrogen peroxide.

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 agenda. None was declared by the working group members.

5. Agreement of the draft minutes from WG II 2019

Comments on the draft minutes were received on

- BPF HYPRED's octanoic acid based products
- Hydrogen Peroxide Family 1

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

The minutes of the working group meeting II in 2019 have been agreed by the working group members.

6. Discussions on active substances

6.1. Peroxyoctanoic acid

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

6.2. Copper (massive)

Chair invited the applicant to the meeting and informed the company representatives that the ECHA code of conduct has to be followed, hence they are invited to the meeting as an observer only who might respond to questions of working group members. Furthermore applicant was informed that the meeting is recorded but only for the purpose to draft the minutes; the recordings will not be released to anybody outside ECHA. The recordings will be destroyed after the agreement of the minutes. Any further recording of the meeting is not allowed and the mobile phones have to be switched off.

The chair explained that the reference specifications of copper (massive) has been discussed at the Biocidal Products Committee (BPC) which requested a modification of the proposed reference specification. Hence the reference specifications has been modified by ECHA in cooperation with the eCA (France) and the applicant. The specification set according to the copper grade 'Cu-ETP' included for example in the European Standard EN 13601:2013. It was noted that the European Standard EN 13601:2013 includes a multitude of copper grades with different specifications. Only the copper grade with the material designation of symbol: Cu-ETP and number: CW004A is considered for the reference specification of copper (massive), other grades indicated in this norm are not reference specifications. The physical parameters indicated in this norm shall not be considered for the reference specification.

It was agreed by the APCP working group that copper (massive) can be supplied by all suppliers and manufacturers that comply with the copper grade Cu-ETO and number CW004A. Hence, the assessment of technical equivalence is not required for this active substance. However, companies applying for product authorisation have to attach certificates of analyses (CoA) for demonstrating that the copper (massive) used in the biocidal products complies with this reference specification. The CoA should include all information as outlined in the Technical Agreements of Biocides (TAB).

7. Discussions on technical and scientific issues and outcome of e-consultations

7.1 Analytical profile and reference specification of Lavender, *Lavandula hybrid* extract

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

7.2 Storage stability of precursors in tanks

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

7.3 Identity of silver chloride

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

7.4 In situ generated peracetic acid – 5-batch analysis

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

8. AoB

Post-approval information: Analytical methods for active chlorine releaser

Analytical methods for monitoring active chlorine releasing substances have been indicated as post-approval requirement. In the meanwhile member states received applications for products authorisation, hence clarification on the state of play of this post-approval requirements was requested. The chair explained that these analytical methods have been provided by the applicants and evaluated by the eCA. They are currently under verification by ECHA but they will be provided to the members of the BPC for commenting. Therefore, the APCP working group members should contact their BPC member if they wish to peer-review the analytical methods.

Hydrogen peroxide radicals generated from hydrogen peroxide

Clarification on the state of play of hydrogen peroxide radicals from hydrogen peroxide was requested. During the discussion at the APCP working group meeting I in 2018, it was raised whether hydrogen peroxide radicals generated by a device using an electrical current are covered by the approval of hydrogen peroxide or whether these hydrogen peroxide radicals generated from hydrogen peroxide should be regarded as an active substance of its own. An e-consultation, including the other working groups (environment, human health and efficacy), was initiated. The chair clarified that ECHA is currently evaluating the received replies and preparing a document for the meeting of competent authorities where a decision should be made whether hydrogen peroxide radicals generated from hydrogen peroxide is an active substance of its own.

Annex 1 - List of attendees

Country	Members of WG
Austria	ZUTZ Christoph
Austria	KUEHRER Lukas
Austria	GHOBRIAL Michael
Finland	VUORENSOLA Katariina
Finland	KARHI Kimmo
France	WEBER Philippe
Germany	MŰHLE Ulrike
Greece	TZANETOU Evangelia
Greece	GATOS Panagiotis
Italy	CATALDI Lucilla
Latvia	IGAUNE Ieva
Norway	HELGERUD Trygve
Norway	STAVE SEKKENES Marianne
Poland	HUSZAŁ Sylwester
Portugal	BORGES Teresa
Slovenia	VELIKONJA BOLTA Špela
Sweden	OESTERWALL Christoffer
Sweden	ALPE MIA
Switzerland	AESCHBACHER Michael
The Netherlands	HUIZING Tjaart-Jan
United Kingdom	WARBURTON Anthony

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

Company	Observer
Ecolab	GRAEF Helena for POOA
Ecolab	KOZIOL Felix for POOA
Necontec	McGrath Mike for copper (massive)
Regulatory Compliance Limited	Carol Mackie for copper (massive)
Neudorff	KLUG Thomas for L. extract
SCC GmbH	GALLER Martina for L. extract
Christeyns	DOSOGNE Hilde for PAA
hollu	SPIELDENER Stefan for PAA
Prosacon	TCHACHOJAN Viktoria for PAA

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

WG-III-2019

Final minutes

10 September 2019

Minutes of Efficacy WG-III-2019

27-28 May 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 28th Efficacy WG meeting. There were 5 core members, 3 alternate members and 13 flexible members who participated in the meeting. In addition 5 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. FR proposed to discuss an item concerning renewal of PT14 authorisations under AOB. 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-II-2019 draft minutes. The comments were agreed in their revised form by the EFF WG, and the revised draft minutes were agreed upon. With reference to the comment made by DE at the meeting, ECHA checked the recordings and concluded that the draft minutes were correct. Therefore this additional comment will not be taken into account, and the revised version agreed at the meeting is treated as final.

6. Discussion of Active Substances

6.1. Peroxyoctanoic acid PTs 2-4 (eCA FR)

There was one provisionally closed point in the discussion table, which was not opened by the EFF WG during the meeting. The EFF WG agreed with the evaluation made by the eCA. Please refer to the conclusions in S-CIRCABC.

6.2. Early WG on Ozone PTs 2, 4, 5 and 11 (eCA DE)

DE CA is evaluating the active substance ozone, and first discussion on the required efficacy data took place in an early WG at EFF WG-IV-2017. After submission and evaluation of new efficacy studies DE had three questions to the EFF WG, which were all agreed upon. Please refer to the conclusions in S-CIRCABC.

7. Discussion of Union Authorisations

7.1. Early WG of general interest

Please refer to the conclusions in S-CIRCABC.

7.2. Early WG of general interest

Please refer to the conclusions in S-CIRCABC.

8. Technical and guidance related issues

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

The discussion on Appendix 4 - Overview of standards, test conditions and pass criteria (PT 1-5) continued from WG-II-2019. Discussion was carried on from whether prEN/fprEN standards can be referred to. Concerns were expressed about whether the prEN/fprEN versions are still subject to changes, and whether they are available in all MS. The CEN experts clarified that changes may occur in the prEN versions, but that the changes are always recorded. For fprEN versions only editorial changes are possible. The prEN versions are available in English, French and German from the CEN webpage, but not necessarily from national standardisation bodies. Dates of publication are given, but could vary with the different languages. It was brought up that even if changes to prEN versions are well recorded, it would complicate the evaluation to take into account all different versions and dates for their applicability, due to the agreement on the exact timelines of guidance applicability. For the time being the issue was left open, and it was agreed that CEN will clarify further the development process for EN standards, and that a link to the relevant CEN webpage will be added to ECHA Efficacy webpage.

Due to some discrepancies in standards CEN recommended not to apply current EN 14476 (viruses) or EN 14348 (mycobacteria) standards for hygienic handwash products. It was agreed that CEN will flag the issue for their September WG1 meetings, and will inform ECHA on the proposed way forward.

Another intensively discussed topic was whether three levels of virucidal activity (activity against enveloped viruses, limited spectrum virucidal activity, virucidal activity) should be applied also for hard surface disinfection, and not only hand disinfection, as has been the case so far (see Technical Agreements for Biocides; Limited virucidal activity / WGII2016). The (f)prEN 14476 (Suspension test for viruses in the medical area) and EN 16777:2018 (Surface test for viruses in the medical area) introduce three levels of activity for surface disinfection. The point was left open for ad hoc follow-up. CEN will update ECHA on the status of the publication of (f)prEN 14476.

It was noted that the log reductions in EN 16615 (Surface test with mechanical action for medical area) are too high for non-medical applications. On the other hand it was pointed out that no other surface disinfection test with mechanical action is available. It was agreed that CEN experts will consult their WG3, responsible for developing this standard, whether the level of inoculum or the required log reduction in EN 16615 could be modified before a test for non-medical area will be developed. The EFF WG also pointed out that there is not a harmonised agreement between MS of what is included in "healthcare area" and "medically indicated". It was agreed that for the next discussion on Appendix 4 the definitions from other relevant regulations, especially the Medical device regulation, will be consulted.

In addition it was agreed to add sporicidal activity for PT2 hard surface and instrument disinfection. The contact time for PT2 and PT4 hard surface and PT2 instrument disinfection was agreed to be amended into "as claimed", but indicating in a footnote that the minimum contact time in the EN standards needs to be respected. For PT2 hard surface and instrument disinfection also the temperature was agreed to be amended into "as claimed", making in the footnote reference to temperature recommendations in the respective standards, EN 14885, and relevant chapter in BPR Vol II B+C guidance. Regarding PT2 textile disinfection it was agreed that FR will check whether any other applicable standards besides EN 16616 and ASTM standards exist, and industry will send a concrete proposal regarding their comment on aligning between this section and EN 14885.

Also a number of other comments were agreed upon. The Chair informed that the discussion of Appendix 4 is planned to be continued in EFF WG-IV-2019 in September.

8.2. Testing of different surface applications methods

In the framework of several Union authorisation applications it has become apparent that different approaches are taken by MSs concerning the evaluation of various surface application methods for disinfection in PT2 and PT4. DE had prepared a document listing the potential application methods, along with proposals of applicable EN standards. Cefic indicated that hand dishwashing is missing from the list, but it was agreed not to amend the list since dishwashing, especially by hand, is quite a specific application method, and it was considered more important to reach a harmonised view on the more common application methods.

The EFF WG agreed that EN 13697 is recommended for spraying, pouring and foaming, as well as for brushing application. For wiping (RTU wipes, specified/unspecified soaked wipes) and mopping (RTU mops, specified/unspecified soaked mops) it was agreed that EN 16615 is the most appropriate test method, since disinfection is carried out with mechanical action, which is not simulated in EN 13697.

Cases where the product is applied onto surface by spraying/pouring, followed by wiping/mopping of the surfacel, were identified as exceptions, because wiping/mopping in such cases is considered as a way of distributing the product without any real mechanical action. For these exceptions EN 13697 was considered applicable.

The EFF WG also noted that the applicant should be responsible for indicating whether wiping or mopping is only for distribution of the product or whether mechanical action should be involved. CEN confirmed under agenda item 8.1 that it is not recommended to use specified mop materials in EN 16615, but rather the standard wipe material.

The EFF WG agreed that for ongoing applications both EN 13697 and EN 16615 are acceptable in borderline cases. The decision for harmonised interpretation of guidance can be applied only for applications submitted after the decision has been published in public S-CIRCABC.

8.3. Contact time (CT) for wipes

In the framework of several Union authorisation applications it has also become apparent that there are differing views as to how the CT for wiping/mopping applications is defined, and whether the surface needs to remain wet during the whole CT. AT had prepared a document with some proposals, but it was agreed that the document will be revised by AT after a meeting with ASOs, and the revised version will be discussed in EFF WG.

8.4. Test for disinfectants used in the veterinary/medical areas

DE had prepared a document related to efficacy test used in medical areas. For the time being only one test is required to prove efficacy of disinfectant, and a concern was raised whether it is sufficient, especially in medical areas where vulnerable persons are present. Therefore DE proposed to require two independent test for disinfectants in medical area. The EFF WG agreed that there are some uncertainties or measurement errors, so more repetitions would be helpful. Nevertheless, some MS pointed out that even CEN guideline does not require repetitions, so such a requirement would be contradictory to the current EN standards, and it would significantly increase the cost of efficacy tests. Furthermore, some MS were of the opinion that in the current practice the probability that an inefficient product will pass the test is not high, as P2S1 and P2S2 (if available) tests are required with three different concentrations and high (5 log) reduction. The tiered approach proposed in the efficacy guidance gives a certain level of precision and assurance of efficacy. IND also pointed out that the 5 log reduction is required for the single, worst case test organism, and usually in EN standards four test organisms are required. Taking into account the major objections raised during the meeting DE will revise the proposal and submit it again for discussion in the near future.

9.1. Other information and lessons learned

The Chair informed that the next EFF WG meeting will take place 24-25 September as a physical meeting in Helsinki. Some of the EFF WG members indicated that OECD meeting

in Korea is organised 23-24 September and asked if it would be possible to organise the EFF WG meeting a week earlier. ECHA will check the available dates and inform the WG members accordingly.

ECHA post-meeting note: The EFF WGIV2019 meeting will be organised 18-20 September 2019.

The other information was related to early WG discussions. ECHA presented the necessary information which has to be submitted when an eCA is requesting an early WG discussion. ECHA has prepared a new template for early WG discussion, a link to this document will be sent to the EFF WG members. As usual a brief overview of ongoing e-consultations was given.

9.2. Active substances workshop: Feedback and actions

ECHA provided information from the active substances (AS) workshop, which took place in Helsinki in February 2019. It was 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 proposals were presented to the EFF WG. EFF WG members were mainly interested in web streaming possibility of the WG meetings. ECHA informed that this possibility is still under consideration of the WG Chairs, and no final decision is yet available. Other comment was made in relation to reduction of uses during AS approval. It was indicated that there was no consensus for that, some workshop participants considered that it is better to approve more uses at AS approval stage and benefit from this at product authorisation stage. Furthermore for Treated Articles the AS approval stage is the only one possibility to check the intended uses. The EFF WG members were also a bit worried on how the help for other eCAs will be organised, hoping that it will be on a voluntary basis. ECHA explained that the idea of work sharing has been brought up by some MSs in order to compensate for a lack of expertise in certain areas. For the time being there is no clear proposal for such cooperation between MSs; ECHA will work on it.

9.3 PT14 renewals

This issue was raised by FR, who authorised PT14 products and, according to applicable guidance, accepted the application rates which do not correspond to those tested in the field tests, e.g. claim is made for 40 g of product/bait station and in the field test the efficacious application rate is 100 g of product/bait station. Now the "Transitional Guidance on Efficacy Assessment for Product Type 14 Rodenticides – December 2016" is applicable, and the claimed application rates should be consistent with those tested in the field tests. FR raised this issue to make the other MSs aware that even though the first batch of PT14 authorisations is already renewed based on the previous guidance, the newly applicable guidance should now be taken into account by all MSs. It was agreed that FR will send to ECHA brief information concerning this issue, and ECHA will inform/remind all EFF WG members about applicability of this respective efficacy guidance in relation to the amount of bait applied at each bait point.

List of Attendees

Efficacy Working Group

Core members
ZUTZ Christoph (AT)
GIATROPOULOS Athanasios (EL)
ATTIG Isabelle (FR)
HAMEL Darka (HR)
SMITH Ryan (UK)
Alternate members
GUNNEWIG Kathrin (DE)
MAXIMILIEN Yann (FR)
WORM Petra (NL)
Flexible members
PEELMAN Natania (BE)
GURBA Alexandre (CH)
PECINKOVA Martina (CZ)
FISCHER Juliane (DE)
JANSEN Irina (DE)
CLEYTON JØRGENSEN Charlotte (DK)
ILMARINEN Kaja (EE)
NIEMINEN Timo (FI)
RYDMAN Elina (FI)
MEZULE Linda (LV)

Flexible members
GĄSZCZYK Małgorzata (PL)
FRANK Ulrike (SE)
MALMGREN Birgitta (SE)
ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
SCHAKIR Yasmin
HONKA Anni
Applicants
Ecolab
EurO3zon
Experts
ROQUES Christine (CEN)
STEINHAUER Katrin (CEN)
Stakeholders
KASURINEN Ossi (CEFIC)
ASHWORTH David (CEFIC expert)
BIRCHENOUGH Peter (AISE expert)

Environment WG-III-2019 & WebEx follow up
Final minutes
22 October 2019

Minutes of Environment WG-III-2019

& WebEx follow up

23-24 May 2019 / 11 June 2019

Meetings of the Environmental Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 25 participants present, of which five were core members (one represented by alternate), fifteen flexible members, two rapporteurs and one adviser. Two representatives from accredited stakeholder organisation was present part time. Applicants were registered for their specific substance discussions.

At the WebEx follow up meeting nineteen WG members participated.

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. The chair and the deputy chair declared an interest with two of the cases which however were not considered as conflict of interest.

5. Agreement of the draft minutes from WG-II-2019

The minutes were agreed without further discussion.

6. Discussion of Active Substances

6.1 Peroxyoctanoic acid (eCA FR) – PT 2-4

Seven points were discussed related to exposure- and effect assessment, all points were closed.

Actions:

- The **eCA** will include the ED assessment and a clear conclusion for non-target organisms in the CAR.
- The **eCA** to include the evaluation of one study in the DOC IIIA. The eCA will also include further argumentation to support the use of the read-across.
- In a future discussion when the guidance on aggregated exposure assessment is in place, it needs to be checked if the situation for PT 3 is clearly defined. Currently the aggregated exposure assessment is - in the absence of an agreed guidance - not used for decision making. **Action for the ENV WG**.
- The **eCA** and **SECR** to cross check the proposed classification, the outcome will be reported in the draft case related minutes as a post meeting note.

6.2 Early WG: Follow up on monochloramines generated in situ (eCA AT, FR, SE, UK) - PT 5, 6, 11, 12

A harmonised approach was being sought among the different eCAs evaluating monochloramine (MCA) generated in situ cases. An e-consultation was conducted among the eCAs to compile the available information on the a.s., precursors, DBPs and impurities. This was the second discussion at a WG meeting (see early WG discussion at ENV WG-IV-2018, item 5.2).

Eleven points were discussed related to exposure- as well as effect assessment. One point remained open.

Actions:

- The details on one specific study requirements will be discussed and agreed between the four eCAs.
- The eCAs will consider the comments received during the WG and will keep working in the assessment of the water compartment
- A follow up meeting between the eCAs will be organised by SECR.

6.3 Early WG: PBT assessment Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide (eCA DE) - PT 18

Three points related to the PBT assessment were discussed, all points were closed.

Actions:

- **eCA** to prepare the consultation for the PBT-EG. SECR will advise on the procedural aspects of the consultation.

6.4 Pyrethroid common metabolites (SECR)

Following an agreement at the BPC-24, it was decided to create a harmonised list of endpoints (LoEP) for the common metabolites of pyrethroid substances. The first draft of the data matrix and the DE discussion paper were commented in an e-consultation in April 2019. The outcome and the remaining open points were presented at the WG meeting.

The procedural aspects identified, such as dissemination of the LoEP to applicants, data sharing issues, implementation period, and maintenance of the data matrix, will be clarified separately outside the WG discussion.

Three items were discussed. One point remained open which will be followed up first ECHA-internally.

Actions:

- Concerning substance identity and naming of the metabolites, **SECR** to follow-up internally in consultation with APCP and TOX as necessary.

Additional items discussed at the WebEx follow up

W5.1 Follow up e-consultation of NL on new endpoints for DEPAP (Bardap 26) (eCA NL)

Eight points mainly related to new information provided after approval of the active substance were discussed. Two action points were defined, to be followed up by the eCA and the applicant, no ad-hoc follow up per se was necessary.

W5.2 Follow up e-consultation of IT on new endpoints for Bardap 26 (eCA IT)

The item was only preliminary discussed and will be followed up at WG-IV-2019. Seven points, mainly related to new information provided after approval of the active substance, were discussed.

W5.3 PBT assessment permethrin (eCA IE)

Four points were discussed related to the PBT assessment of permethrin. All points were closed, one action point for the renewal stage of the substance was determined.

7. Technical and guidance related issues

7.1 Overview on guidance

SECR presented the status on guidance development, issues identified for the AHEE and e-consultations. Updates from WG members during the meeting have been included after the WG meeting (see updated table in **Appendix 2** below).

7.2 Confirmation of PT 8 EG meeting agreements

The conclusions of the PT 8 expert group were presented to the ENV WG for confirmation together with the outcome of an e-consultation on items that could not be discussed at the EG meeting. The detailed conclusions are provided in **Appendix 3** below. In the following only the agreed actions are summarised.

Actions:
- **EBPF/EWPM** to provide requested information on items 1a, 5 by end of August 2019.
- **SECR** to schedule items 1a, 1b, 2, 5, 9, 10, 12 at AHEE-3 (September 2019).
- **SECR** to send conclusions on RMM and a related question to BPC (items 3a, 3b).
- **SECR** to contact CEPE (item 9, 10).

7.3 *Item was postponed*

7.4 Further clarification on the use of PECtwa/ini in soil

The SECR presented a paper with the aim of discussing the use of PECtwa and PECinitial for soil risk assessment in relation to the available PNEC values in cases of indirect exposure to soil via sewage sludge or manure or to a limited extent in cases of direct exposure to soil.

The WG agreed that there is currently no need for a clarification of the guidance, since the guidance provided in Vol. IV Part B+C is considered clear enough. The proposed proposal was not endorsed.
Nevertheless it was agreed to initiate an e-consultation to collect feedback from MS on cases of substances, where the MS had issues in applying the existing guidance.

The following questions should also be added to the e-consultation: In case PECini is calculated should the actual PEC be used for the 10 previous years of sewage (manure?) application instead of the PECtwa? The item should be explained in more detail in the e/consultation. The initial feedback was that the TWA calculation is correct.

Actions:
- **SECR** to initiate two e-consultations on the points discussed at the WG meeting.

7.5 Update of guidance for in situ generated active substances and their precursors

SECR presented a presentation on the current status. The WG recommendation was published at the ECHA website:

https://echa.europa.eu/documents/10162/13564/situ_as_precursors_wg_recommendation_+2017_en.pdf

There is a COM request for further guidance to address the technical challenges of authorisation of biocidal products for generation of an active substance in situ, the preferred approach was to update to the current recommendation. Following a gap analysis the ENV WG concluded in a previous WG meeting that no update is needed, whereas the TOX WG identified certain items that may be relevant also for the Environment related sections.

Input on the following questions was collected:

- Do you agree that issues identified by TOX for development are relevant also for ENV
- Further issues to be elaborated?
- Can we progress on these issues at this point in time?
- Volunteers to provide drafting?
- Need for cooperation with TOX?

7.6 Further guidance on substances of concern

SECR presented the document that was gathering together open questions regarding substances of concern. The intention is to identify as far as possible the questions for which guidance or clarifications are needed, and as the next step, to identify the appropriate bodies to provide the answers. The document will be updated based on the input provided in the different WGs, and will then be provided for commenting in order to identify 1) possible solutions to some of the questions, 2) volunteers to clarify some specific questions and 3) further open questions.

8. AOB

8.1 Other information & lessons learned

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

The **next ENV WG meeting** is scheduled for 26-27 September (physical meeting), the **next AHEE** is scheduled for 25 September 2019 (physical meeting).

Early WG meetings vs. e-consultations
Early WG meetings can take place for AS and UA cases.
Procedure for any other cases specific discussion (where necessary):

- MS to prepare a document for an e-consultation and provide it with a proposed consultation deadline to SECR.
- SECR to launch the e-consultation via a S-CIRCABC newsgroup.
- MS to evaluate the outcome of the e-consultation and provide a summary + conclusion to SECR (=> *new information after AS approval*).
- If outcome clear: SECR to distribute the conclusion between MS *(=> new information after AS approval*).
- If outcome unclear: E-consultation can be followed by a document to be discussed at the WG if needed.

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

- 4-5 June (confirmed)
- 1-3 October
- 3-5 December

The deadline for confirming the substances for the October ED EG is 31 July 2019. SECR asked the members to confirm the substances by sending an e-mail to ed_eg@echa.europa.eu.
SECR informed that the document *Assessment of ED properties of co-formulants in biocidal products – draft instructions for applicants* has been published[1]. Another document providing instructions for MSCAs has been prepared by BE and FR and was under commenting until 3 June 2019.

Bees risk assessment
E-consultation for RMM is in CH and DE hands to finalise and be sent to CG. EFSA and ECHA has received a mandate to develop a guidance for RA for bees, EFSA will start working on it soon

- Gathering experts for a dedicated WG_Bees
- Writing a draft outline
- Expected deadlines (Q32019-Q42021)

ECHA can participate as observer with the possibility of bringing issues or questions to the group. COM insist in consistency between Biocides and PPP in regards to bee assessment, one single guidance is not an option.

How to apply ECHA's practical guide 'How to use and report (Q)SARs' for the assessment of substances under BPR
SECR informed that the document will be soon published on the ECHA Webpage. It contains a comparison of BPR and REACH data requirements and guidance, full correspondence of texts and a reporting template.

Some lessons learned:

SECR provided the following **clarification on the use of functional mailboxes (FMB)**:

- In case of questions related to WG membership/changes in membership or any other administrative questions concerning the WG meeting: contact ECHA WG FMB (bpc-wgs@echa.europa.eu)
- For any scientific or technical content related issues (e.g. request for e-consultations, case or guidance related questions): contact ENV FMB (bpc-environmentalexposure@echa.europa.eu)

Please always copy in the chair for any scientific or technical content related issues.

Table documents & items for information: SECR reminded that these are to be provided by applicants/ASOs **two days** before the meeting at the latest (see RoP) - if provided later, there is no guarantee that WG members can have a look before the meeting.

8.2 Active substance workshop: Increasing WGs efficiency: 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

[1] https://webgate.ec.europa.eu/s-circabc/sd/d/dc42856d-9209-44bc-8595-b8f5a185664c/CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants.pdf

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 and the current lack of submission of the draft CARs.

SECR presented the input and actions suggested in the break-out group that discussed the efficiency of the WGs, as well as the on-going actions that have been launched following the workshop. For details, see the presentation available to MSCAs and ASOs in S-CIRCABC.

In a tour the table additional items were collected which will be further evaluated by SECR.

8.3 Update on ongoing EUSES projects

The Chair informed the WG that the official release of EUSES 2.2.0 has been postponed to September, awaiting legal issues related to the ongoing ownership transfer of EUSES from JRC to ECHA to be clarified.

In the meantime implementation continued and the following additional scenarios were added:

- 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)
- Default scenario

The beta-version was shared with MSs and ASOs, SECR thanked the testers for their feedback.

Appendices:

Appendix 1: List of participants

Core members:

- (DE) Daniel **FREIN**
- (FR) Stéphanie ALEXANDRE
- (IE) Helena JOYCE
- (NL) Karlijn HOLTHAUS – Alternate member
- (UK) Neil HARPER

Flexible members:

- Aamodt Solveig (NO)
- Boquist Pernilla (SE)
- Cougnon Thomas (BE)
- de la Flor Tejero Ignacio (ES)
- Gibson Richard (UK)
- Hadam Anna (PL)
- Kunz Petra (CH)
- Leroy Celine (BE)
- Lozach Jerome (FR)
- Michaelis Katja (DE)
- Molnarova Jana (SK)
- Muri Petra (SI)
- Pasanen Jaana (FI)
- Penttinen Sari (FI)
- Podlaska Agnieszka (PL)

Rapporteurs :

- Altmann Dominik (AT)
- Persson Johan (SE)

Member's advisor:

- Loskyll Julia (DE)

ASOs:

- Paul **MASON** (CEFIC expert) – all non-confidential items
- Naomi **YOUNG** (CEFIC expert) – only for agenda point 7.2 Confirmation of PT 8 EG meeting agreements

Appendix 2: Item 7.1 - Overview on guidance

Note:

- Guidance related items unchanged since WG-III-2019 are highlighted in grey shading.
- Closed items are ~~stroke through~~.

WG	Title	Current leader	Status	Actions to follow	Type of document	Priority	Prioritisation justification
n.r.	Inclusion of the finalised fish net scenario in MAMPEC	ECHA	On hold until EUSES projects are finalised (software contract needed). Note that this is no guidance development as such but IT development	ECHA to set up a contract with an external contractor	IT	Low	Scenario finalised and in use
ENV-WG	Guidance on aggregated exposure assessment	DE	The final draft of the guidance was provided by DE to ECHA.	Legal situation currently under evaluation by ECHA	Guidance	High	Need for harmonised methodology for this BPR requirement
ENV-WG	Development of guidance for bees and non-target arthropods --> CG (2017) --> WG-IV-2018 --> WG-II-2019	DE+CH	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 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. DE/CH have provided a revised document for discussion and agreement at WG-II-2019.	Follow up to be decided after a planned telcon with EFSA	Guidance	High	No guidance available

WG	Title	Current leader	Status	Actions to follow	Type of document	Priority	Prioritisation justification
ENV-WG	PT 6: Corrections of the ESD for PT 6 --> WG-IV-2018 --> AHEE-2 - AP4.1	ECHA	Revised ESD finalised, agreed corrections have been implemented in the ESD. The corrections are also implemented in EUSES 2.2.0.	ECHA to publish revised ESD	ESD	High	Updated in EUSES - guidance should reflect software status
ENV-WG	Invasive exotic mosquito control with adulticides --> AHEE-2 - AP4.7	NL	Proposal of NL was discussed at AHEE-2 (December 2018). Agreed actions at AHEE-2: - Some members (DE, CH) to consult PPP experts for items interception, bees and NTA. - ECHA and NL to collect any relevant information from other MS that were not present during AHEE. - NL to make a consultation at the CG through their CG representative to collect feedback from other MS.	Follow up on agreed actions ongoing: CH provided feedback on 18 March 2019, NL to collect via CG feedback from other MS	TAB	Low	No emission scenario available but niche scenario
ENV-WG	Guidance on disinfectant by-products formed during the use of products in product types that are not yet addressed (i.e. uses resulting in contact with food or drinking water). --> CA meeting (SE feedback)	no volunteer	OPEN Guidance available prepared by NL, exstension of existing guidance needed.	WG member to take over item to be assigned.	Guidance	High	For some PTs no guidance available

WG	Title	Current leader	Status	Actions to follow	Type of document	Priority	Prioritisation justification
ENV-WG	Sediment assessment --> PEG Vol IV Part B+C	ECHA	During the revision of Vol IV part B+C several aproaches were presented to refine the risk assessment for the sediment compartment. It was agreed at the time of the PEG that there wasn't enough time to look into those and that they would be discussed after the PEG. Both items have gone through several discussions and would need to be finalised	Continue the discussions	TAB	Low	Existing guidance currently in place
ENV-WG	Update of Guidance Vol IV Part A	ECHA	Start to collect items for a future update (planned for 2020)	Prepare a list of items that need update. First the BPR annex needs to be agreed	Guidance	Medium	Many changes have accored since the previous version
ENV-WG	Revision of guidance on data requirements for in-situ generated substances and their precursors	ECHA	Identification if there is a need for updateing the existing document	Discussion at WG-III-2019	Guidance	Medium	Guidance currently in place
AHEE	PT 2: Disinfection of drip irrigation water (PT 2) --> AHEE-2 - AP4.1	DE	The proposals was agreed at AHEE-2.	Publication	TAB	Medium	Missing emission scenario however niche application

WG	Title	Current leader	Status	Actions to follow	Type of document	Priority	Prioritisation justification
AHEE	PT 2/PT 4: Negligible environmental exposure due to the disinfection of surfaces with RTU wipes --> AHEE-2 - AP4.1	DE	The proposals was agreed at AHEE-2.	Publication	TAB	Medium	Missing emission scenario however niche application
AHEE	PT 3: Scenario for disinfection in aquaculture --> Disinfection project/EMA aquaculture workshop	ECHA	ECHA contracted out the preparation of a first scenario proposal. First discussion took place at WG-I-2017, comments received during subsequent commenting period were added. Preparation of revised version currently on hold until EUSES projects are finalised.	Revision of existing draft scenario	TAB	Low	Low number of uses
AHEE	PT3/PT18: Exposure assessment of metabolites in the terrestrial compartment - indirect exposure via manure/slurry application on agricultural land --> AHEE-2 - AP4.11	DE	The proposal was greed at AHEE-2, DE provided the final document.	Publication	TAB	Medium	Extension of existing guidance

WG	Title	Current leader	Status	Actions to follow	Type of document	Priority	Prioritisation justification
AHEE	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	NL volunteered to take over the item. Timing to be defined.	To be initiated	TAB	Medium	Refinement option for product authorisation for PT 4 ongoing/comin g
AHEE	PT 4: Derivation of a default value for Felim for certain type of substances --> WG-I-2018 – item 7.6 --> AHEE-2 - AP4.4	NL	NL proposal was discussed and agreed at AHEE-2 (December 2018), final document was provided by NL for publication.	Publication	TAB	Medium	Refinemt option for product authorisation for PT 4 ongoing/comin g
AHEE	PT 6: Development of an emission scenario for the preservation of unrefined fuels --> WG-V-2015 – item 7.3, WG-II-2018 – item 7.3d	NL	E-consultation initiated on agreed changes, deadline for providing feedback was 1 April 2019. Revisions by NL were agreed by AHEE members, explanations on specific SimpleTreat settings to be added by NL.	Publication	TAB	Medium	Missing emission scenario however niche application

WG	Title	Current leader	Status	Actions to follow	Type of document	Priority	Prioritisation justification
AHEE	PT 8: PECsediment – direct release to surface water --> WG-II-2018 – item 7.3c --> AHEE-2 – item 4.6	NL	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 PECsediment from a static pond-water system and provided background information for the discussion. The AHEE agreed to follow up this item via an e-consultation, NL revised the document after the e-consultation.	Written procedure to finalise the document ongoing	TAB	Medium	Unclear ESD, which equations should be used for risk assessment
AHEE	PT 8: PEC calculation service life sediment – direct release to surface water --> WG-II-2018 – item 7.3g --> WG-IV-2018 – item 6.3 --> AHEE-2 - AP4.10 --> PT 8 EG meeting	NL	Discussion at WG-II-2018, procedure with regard to PECTWA agreed, approaches for leaching calculation discussed at WG-IV-2018, still open. Discusssion at AHEE-2 (December 2018): NL presented a document that summarises the differences between two approaches to calculate the concentration at the end of the emission period.	Closed at PT 8 EG meeting, confirmation by ENV WG at WG-III-2019	TAB	Medium	Unclear ESD, which equations should be used for risk assessment
AHEE	PT 11: Which fraction should be used to calculate the PEC in soil following deposition from air? --> WG-IV-2016 – item 6.3 --> AHEE-2 - AP4.2	NL	NL prepared a document for AHEE-2 which explains and evaluates the currently available methods to calculate PECsoil 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	NL to revise the document after the e-consultation. Written procedure to finalise the document to be initiated by ECHA	TAB	Medium	Unclear ESD, risk assessment currently overestimates PEC in soil

WG	Title	Current leader	Status	Actions to follow	Type of document	Priority	Prioritisation justification
			the item via an e-consultation. SECR initiated the e-consultation among the AHEE members.				
AHEE	PT 11: Refinement options for once through and large recirculating systems --> WG-II-2016 – item 6.8/6.9 --> AHEE-2 – item 4.3	FR	The proposal prepared by FR was discussed at AHEE-2 (December 2018).	FR to revise the equation and input parameters based on the comments received	TAB	Medium	Refinement option for product authorisation for PT 11 ongoing/comin g
AHEE	PT 18: Use of treated water for irrigation of private gardens - exposure estimation of soil compartment --> AHEE-2	DE	Discussed and agreed at AHEE-2, DE provided the final document. SECR initiated a written procedure on further changes proposed by DE.	Publication	TAB	Medium	Missing emission scenario however niche application
AHEE	PT 18: Use of treated water for irrigation of private gardens --> AHEE-2 - AP4.12	DE	The proposals by DE were discussed at AHEE-2 (December 2018). Further changes were made in the document after the AHEE meeting, to be confirmed by the AHEE.	Written procedure to finalise the document ongoing	TAB	Medium	Missing emission scenario however niche application

WG	Title	Current leader	Status	Actions to follow	Type of document	Priority	Prioritisation justification
AHEE	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	DE/UK volunteered to take over the item (update of PBT guidance to be taken into account). Timing to be defined. Potentially for discussion at AHEE-3 (September 2019)?	To be initiated	TAB	Low	Currently guidance in place, only a clarficaiton is needed
AHEE	Direct emission to surface water – Definition of Tier 2 --> WG-II-2018 – item 7.2 --> AHEE-2 - AP4.5	NL	NL mapped places of direct release to surface water by-passing an STP as preparatory work for a Tier 2 preparation. NL proposal was discussed at AHEE-2 (December 2018): Concerning RMMs, concerns were raised that they are only applicable to certain product types. It was 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. To be followed up at AHEE-3 (September 2019) - follow up to be discussed with NL.	TAB	Medium	No RMMs in place, critical scenario with regard to direct releases in the environment

WG	Title	Current leader	Status	Actions to follow	Type of document	Priority	Prioritisation justification
AHEE	Simplification of exposure assessment/core scenario development --> WG-II-2018 – item 7.5 --> AHEE-2 - AP4.9	ECHA	In the frame of the EUSES quick fix project, core scenarios have been identified which were presented at AHEE-2.	SECR is currently working on the validation of cores scenario 2. It will be presented at the next AHEE meeting. Preparation of further core scenarios.	TAB/IT	Medium	Currently sufficent guidance in place, core scenarios are meant for harmonisation/ simplification
AHEE	PT 7: Revision of the ESD (inclusion of the formulation step, alignment of equations with A/B tables) --> WG-IV-2016 – item 7.3	no volunteer	OPEN	AHEE member to take over item to be assigned.	TAB	Low	PT related time lines provided in Annex III of the RPR
AHEE	PT 9: Definition/revision of fixation factors for PT 9 – leather applications --> WG-IV-2016 – item 7.3	no volunteer	OPEN	AHEE member to take over item to be assigned.	TAB	Low	PT related time lines provided in Annex III of the RPR
AHEE	PT 9: Concentration in soil in rubber-roof membrane scenario --> WG-IV-2016 – item 7.3	no volunteer	OPEN	AHEE member to take over item to be assigned.	TAB	Low	PT related time lines provided in Annex III of the RPR

WG	Title	Current leader	Status	Actions to follow	Type of document	Priority	Prioritisation justification
AHEE	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	no volunteer	OPEN	AHEE member to take over item to be assigned.	TAB	Medium	PT related time lines provided in Annex III of the RPR
AHEE	PT 18: Development of RTU/small scale application scenario (household and professional use) --> WG-II-2016 – item 6.2	no volunteer	OPEN	AHEE member to take over item to be assigned.	TAB	Medium	PT related time lines provided in Annex III of the RPR
AHEE	PT 18: Development of a proposal on how to use Fsim in an aggregated exposure assessment --> WG-II-2016 – item 6.2	no volunteer	OPEN	AHEE member to take over item to be assigned.	TAB	High	PT related time lines provided in Annex III of the RPR
AHEE	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	no volunteer	OPEN	AHEE member to take over item to be assigned.	TAB	High	PT related time lines provided in Annex III of the RPR

WG	Title	Current leader	Status	Actions to follow	Type of document	Priority	Prioritisation justification
AHEE	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)	ECHA	OPEN	SECR to initiate.	TAB	Low	PT related time lines provided in Annex III of the RPR
AHEE	Focus SWASH: Use of the model for calculation of PEC in sediment (PT 3, run-off from soil) --> WG-IV-2016 – item 7.3	no volunteer	OPEN	AHEE member to take over item to be assigned.	TAB	Medium	PT related time lines provided in Annex III of the RPR

Appendix 3 - Item 7.2 – Confirmation of PT 8 EG meeting agreements

Introduction

It was agreed at AHEE-2 to set up a PT 8 EG meeting in order to discuss questions related to the exposure assessment of PT 8, including the interpretation of leaching studies. Thought starters have been collected from the WG members and feedback was received from FR, DE, NL and BE.

A general requirement identified by several WG members was the need of guidance to interpret the leaching studies and also some rules to extrapolate leaching rates to the different time frames of the assessment, including also kinetic fitting to leaching data and in best case start developing a guidance.

PT 8 EG meeting took place on 27 March 2019, the items for discussion at the PT 8 EG meeting were prioritised at the meeting; the following colour code is applied accordingly in the table below:

Red = high priority
Yellow = medium priority
No highlighting = low priority

The items agreed at the EG meeting (and items on hold awaiting finalisation of documents) are provided in Table 1 for confirmation by AHEE/ENV WG. Feedback on follow up actions is provided *[in brackets and blue writing]*.

Some low priority items could not be discussed at the one-day meeting, they were followed up by two e-consultations. The points covered in the e-consultations together with the feedback received at the consultations are provided in Table 2 below. They are for discussion and agreement by the AHEE/ENV WG.

Table 1: Items agreed at PT 8 EG meeting – for confirmation by the WG

Discussion table – Conclusions PT 8 EG meeting		
a) No	**b) Issue and background** Reference in RCOM	**c) Conclusions and action points**
1a	<u>Harmonised way to assess the read-across for different products regarding leaching</u> FR FR proposes to tackle the harmonisation by preparing a list of co-formulants influencing the leaching, to all be aware of the important things to check in a formulation. These co-formulants could be classified by typical chemical functions (e.g. solvents, surfactant, emulsifier, corrosion, inhibitor, binder, pH stabiliser, mordant, dye, pigment, 'penetration marker' water, repellent and co-solvent). **To be discussed:** Can the WG confirm the high-level assumptions suggested by the EG? *[A second related item raised by NL was covered by an e-consultation and is provided in Table 2 below as point 1b]*	**Conclusion EG:** High level worst case assumption (for worst case product to be used for leaching test): - 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 **Action points EG (deadlines):** EBPF will check if information/overview on binding effects of co-formulants: 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? *[Pending, no feedback received so far]* EBPF: Identifying active substances creating complexes with other actives substances and influencing the leaching behaviour. *[Pending, no feedback received so far]*
		Conclusion WG-III-2019: Proposed high-level list was accepted by the WG, to be extended following information provided by IND.

		EBPF/EWPM aim to have the information available before AHEE-3 (end of August 2019). **Action**: **SECR** to re-schedule item for **AHEE-3**.
2	<u>Equations to calculate PEC in the different environmental compartments</u> FR, DE FR noted that it would be necessary to take stock of the situation (what is concluded, what is pending, which scenarios we have still to work on…). Complete Excel sheets (considering the different refinements proposed in the ESD) would be of added value for MS not experienced in PT 8 equations. Specifically regarding **PECsediment** pond-water (AHEE-2 AP 4.6) DE asked what is the status of this paper is and if it will be discussed at the PT 8 EG. DE sees a need to clearly identify when the new calculation methods can be applied, i.e. which equations in the ESD PT 8 should be substituted by one of the new equations. Can equation 8 from Annex B from AHEE-2_AP4.6 be used to connect both approaches? **To be discussed:** *Item is only provided for information.*	**Conclusion EG:** No conclusion was drawn since the document prepared by NL (PvV) is not yet finalised. **Action points EG (deadlines):** Final version is under preparation by NL (PvV). This item will be forwarded to PvV including the tabled document of EWPM in order to check if there are elements that would need to be taken into account *[Document was forwarded to PvV]*. It needs to be made clear in the document under which situation which equation should be used. Prepare an excel sheet with the revised equations. SECR to check if new equations are already reflected in EUSES 2.2.0. **Conclusion WG-III-2019:** Awaiting the document of **NL**, the item will be discussed at **AHEE-3**. **Action**: **SECR** to re-schedule item for **AHEE-3**.
3a	<u>RMM at product authorisation level</u> FR, DE In order to have a harmonised approach, the following RMMs are proposed:	**Conclusion EG:** Instruction for use/RMM: 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 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

	- Do not use the treated wood near water (is it relevant for industrial treated wood?) - Prevent any release to the environment during the product application phase if carried out in outdoor (especially proposed for products authorized in class 1 and 2 only, without a risk assessment) Concerning UC 1 and 2, DE encountered some product assessments where MS discussed if RMM or instruction for use shall be demanded for these products in order to mitigate emissions to soil. DE proposes to cover all these cases by harmonized instructions for uses, to be discussed at the EG meeting. DE provided a thought starter. **To be discussed:** Can the WG confirm the conclusion of the EG?	contained by covering the ground (e.g. by tarpoline) and disposed of in a safe way. RMM: Concerning the questions if for industrial treated wood under UC 3 the RMM provided in column b 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. **Action points EG (deadlines):** Questions for the BPC: Proposals for RMMs will be forwarded to the BPC for confirmation. *[Pending, BPC consultation will be initiated in June].* In the case of the proposed instruction for use above the question came up if it can be called RMM since no risk assessment as such is performed. DE 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 initiated a WG-wide e-consultation on this matter, see item 3b in Table 2 below].* SECR to check with EFF which UC classification they use *[See item 3b in Table 2 below]*

		Conclusion WG-III-2019: The text on RMM/instruction for use was accepted by the WG but needs to be written more clearly. **Action: SECR** to forward text for confirmation to the **BPC**.
4	<u>Definition of use class (*linked to previous item 3 – RMM*)</u> FR FR questioned what the UCs really represent in term of environmental exposure. For instance, applicants sometimes apply for use class 3A and propose no risk assessment considering that no environmental exposure is foreseen. DE noted that for the assessment of risks due to manual application in UC 1 and UC 2. In the ESD PT 8 no risk assessment for the application methods brushing and spraying in UC 1 and UC 2 is foreseen for curative or preventive applications. However, emissions to soil (and sometimes even surface water) can occur in these use classes. This might be the case for timber, which is already installed within a construction, e.g. for the part of a wooden façade, which is protected by a roof-overhang and thus belongs to UC 2. It is even more likely for timber or wooden commodities, which are treated at another site than the site where they are normally situated/later used. Examples for this might be e.g. an insect infested cupboard (UC 1), which is transported outside of a building and treated outside or timber which is intended for a later use in UC 1 or UC 2, which is treated on bare soil before the installation in a construction etc…. **To be discussed:** *Only for information – please refer to the previous item.*	**Conclusion EG/WG:** Not further discussed, please refer to the previous item.

5	<u>Leaching data from lab leaching studies for UC 4</u> DE DE asks if other member states have already evaluated UC 4 studies and can provide feedback. **To be discussed:** Can the WG confirm the conclusion of the EG?	**Conclusion EG:** 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. **Action points EG (deadlines):** It was noted that guidance is missing on the interpretation of UC 4 leaching tests. Currently no 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, if relevant. *[Pending]*.
		Conclusion WG-III-2019: The WG confirmed the conclusion of the EG. **EBPF/EWPM** aim to have the information available before **AHEE-3** (end of August 2019). **Action**: **SECR** to schedule item for **AHEE-3**.
6	<u>Assessment of wood-preservatives for (long-term) prevention of anti-sapstain</u> DE	**Conclusion EG:** 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 procedure for emission estimation of temporary anti-sapstain products was agreed at WG ENV II 2018. The environmental exposure and risk profile of general preventive anti-sapstain products differs. Hence, the agreed assessment scheme is not applicable for general preventive anti-sapstain products. A thought starter was provided by DE. **To be discussed:** Can the WG confirm the conclusion of the EG?	**Conclusion WG-III-2019:** The WG confirmed the conclusion of the EG.
8	<u>Deriving</u> <u>endpoint from semi-field leaching studies</u> NL A thought starter was provided by NL. The following questions were discussed by the EG: 1. Starting point for the semi-field leaching study (should not start in the summer season) 2. The moisture content of wood should be monitored during the trial 3. Leachate should be analysed after each rain event during the first 60 mm 4. Duration of the test: a semi-field test should last at least two years 5. Other (analytical) discussion points: • Metabolites including those from photodegradation must be included when they may appear in the preserved material or during leaching • Preservatives must be added to the collection vessels to avoid abiotic and biotic degradation, vessels should be protected from sunlight and other UV-sources as well **To be discussed:**	*SECR note*: It is not in the remit of the EG or the WG to change the testing guideline however the following recommendation are provided which may make the outcome of the leaching test more reliable. **Conclusion EG:** Ad 1: It was recommendable to start in autumn. The test should rather not start in the summer season (the starting date is not fixed in the leaching guideline, can therefore 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). Could a solution be to start counting after the first rain event? Not clear. Ad 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 – rather a nice to have than a need to have. Ad 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.

	Can the WG confirm the conclusions of the EG?	Ad 4: It was recommended to run a semi field test for at least two years. Refer also to the guidance discussed at BAM in 2016, reflected in the leaching guidelines for PT 7, 10 where a test duration of two years is recommended (at least 5 test points in the first year and three in the second year). It is recommended that the rain amount of two standard rain years is reached (i.e. 1400 mm). Ad 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 the risk assessment). The following was further recommended: For very sorptive substances a prof of the recovery rate (e.g from the collection container where the substance may adsorb to) is further recommended. In addition during sample storage the container should be protected from sunlight and biotic degradation (by acidification). **Action points EG (deadlines):** Ad 4: Follow up: discuss extrapolation of leaching test results for a longer time, in case no plateau was reached *[Item for **AHEE-3**]*.
		Conclusion WG-III-2019: The WG confirmed the conclusion of the EG. It was further noted that for very sorptive substances instead of a proof of recovery rate reference could be made to the storage stability study and it should be cross-checked if the samples in that study did not come in reaction with the storage material.

11	<u>Interpretation of case specific leaching studies</u> BE In a specific case, the measured concentrations for several active substances are below the LOQ. Therefore no quantitative value is available, but only a qualitative information. For each active, only one sampling day provides a value which may be used. However, with only one sampling point per active, one cannot follow the agreed methodology to derive a leaching rate. It is usually accepted that in case of no leaching test, or when results are not suitable that in a first tier 100% leaching is used in the risk assessment. In this case, this approach is contradictory with the results, which show that leaching is very limited. According to BE, the LOQ should be considered in this case as a value to be taken into account, considering that this arbitrary value is worst case. The following questions were discussed by the EG: 1. In this case, would it be acceptable to set for Time 1 and for Time 2 the value of the LOQ as $*Q_{leach,timex}$? 2. If not, which approach should be followed? 3. In extension to the above case, what to do when, many but not all sampling points are below the LOQ? If the number of sampling days is low (typically 5 or 6), and some of those are below the LOQ, the risk exists that if those points are removed the number of remaining results is too low to be able to derive a curve in order to extrapolate a leaching rate. **To be discussed:** Can the WG confirm the conclusions of the EG?	**Conclusion EG:** Ad 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 (i.e. as the value measured in the leachate). Ad 2: Not relevant, see Ad 1. Ad 3: No sampling points should be excluded, in the described case the LOD/LOQ should be used in the same way as described under Ad 1 above. General comment for BE: check if results are reliable, e.g. check if the issue could be the topcoat and secondly check if any adsorption/degradation in the test vessel took place. Check if there are no experimental artefacts. Is the analytical method reliable? **Conclusion WG-III-2019:** The WG confirmed the conclusion of the EG.
12	<u>Follow up of AHEE – 2 AP 4.10</u> NL	**Conclusion EG:**

	The AHEE agreed that for the time being approach 1 should be used, however approach 2 as optional approach is acceptable (please refer for further information to the AHEE-2 document on AP 4.10). No addition of an AF in the equations of approach 2 is needed, however it should be checked and agreed if there is a need to add an AF on the leaching study case by case, depending on the quality of the leaching study. Discussed was the proposed approach to define a time period for which the exceedance of the PEC/PNEC is acceptable instead of calculating the risk assessment for several time periods. **To be discussed:** For information only, point remains open for AHEE-3.	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 EG (deadlines):** SECR to remind eCA via the CG meeting that we need information on the ERA for PT 8 for Time 2 for the impact assessment. *[Information was provided to CG]*. DE and NL to follow up bilaterally and report the outcome at **AHEE-3** on the comparison of results from approach 1 and 2 (effect on extrapolation for persistent substances). However, the current AHEE conclusion on using approach 1 is not foreseen to be changed at this point in time. *[Item for AHEE-3]*. **Conclusion WG-III-2019:** The WG confirmed the conclusion of the EG. **Action**: **SECR** to schedule follow up of the item for **AHEE-3**.
13	<u>Case specific refinement of topcoated wood</u> FI In the refinement of topcoated wood for a specific case, the following conclusion was drawn during mutual recognition procedure:	**Conclusion EG:** The EG agreed on the proposed approach for a second tier to use the leaching data from the study period from the leaching test with topcoat without adding any AF and use for the extrapolation to the service life the leaching data including the AF (2 or 5 depending on the duration of service life).

	Tier 1 extreme worst case assessment has been undertaken using Assessment Factors of 2 and 5 for topcoated data. Where this exceeds uncoated wood, then the lower values has been used in assessment. Where failures are evident at Risk Characterisation based on this extreme approach, those scenarios have been reconsidered on the basis of Tier 2 realistic cumulative leaching loss (where an AF has been ignored for the fraction of leaching derived from measured data). FI noted, that especially Tier 2 of this approach has not been recorded in the previous Leaching work shop reports. **To be discussed:** Can the WG confirm the conclusion of the EG?	**Conclusion WG-III-2019:** The WG confirmed the conclusion of the WG.

Table 2: Items covered in the EG e-consultation – to be discussed and agreed by the WG

Discussion table – Conclusions PT 8 EG meeting		
a) No	**b) Issue and background** Reference in RCOM	**c) Conclusions and action points**
3b	<u>Follow up of point 3a, related to the need of revising the use classes provided in the OECD ESD for PT 8</u> DE For PT 8 currently the use classes as provided in the OECD ESD for PT 8 (Table 2.1 according to ISO 21887/EN 335: 2009) are used, for which different exposure assessment are performed, considering different receiving environmental compartments.	**Action points EG (deadlines):** DE 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 initiated a WG-wide e-consultation on this matter, see detailed outcome in Annex 1 below].* SECR to check with EFF which UC classification they use *[SECR: EFF is following EN 335:2013* • *Use class 1: situation in which the wood or wood based product is*

	Compared to previous versions the current EN 335:2013 has changed as follows: **UC 3** has been divided into: 3.1: Wood and wood based products will not remain wet for long periods. Water will not accumulate => parts of the former UC 2 (wood for which occasional but not persistent wetting may occur) have been moved to UC 3.1 3.2: Wood and wood-based products will remain wet for long periods. Water may accumulate. **UC 4** is no longer divided into UC 4a and 4b, these were merged into "one" UC 4 => both compartments to be assessed; approval/authorisation should cover both? An e-consultation was initiated amongst the PT 8 EG members on the national situations. **To be discussed:** 1. Concerning UC 3.1 is there a need to change the current risk assessment approach or the OECD ESD for PT 8? 2. Concerning UC 4 is it acceptable to asses and approve only a use with release to one environmental compartment (soil OR surface water)?	*inside a construction, not exposed to the weather and wetting;* • *Use class 2: situation in which the wood or wood-based product is under cover and not exposed to the weather (particularly rain and driven rain) but where occasional, but not persistent, wetting can occur;* • *Use class 3: situation in which the wood or wood-based product is above ground and exposed to the weather (particularly rain)*;* • *Use class 4: situation in which the wood or wood-based product is in direct contact with ground or fresh water;* • *Use class 5: situation in which the wood or wood based product is permanently or regularly submerged in salt water (i.e. seawater and brackish water)].* **Conclusion WG-III-2019:** Ad 1: If the wood outside is protected from rain or wetting, there would be in line with UC 2 no need to perform an assessment. If the wood outdoors may be exposed to rain, an assessment according to UC 3 in the OECD ESD for PT 8 should be performed. The first step is to clarify the intended use to decide if the assessment is according to UC 2 (i.e. no assessment) or UC 3 of the ESD. This means that for UC 3.1 there is always an assessment needed according to UC 3 of the ESD. Ad 2: The WG confirmed that it is still acceptable to assess for UC 4 the environmental compartment separately, i.e. according to the former UCs 4a and 4b in the ESD. Reference can be made to the relevant ISO guideline to create clarity for IND. It is considered important that in the case e.g. only soil is covered (former 4a), the surface water compartment (former 4b) needs to be covered by an RMM (e.g. do not use the wood in direct contact with surface water), since the overall approval will be still only for one UC 4. Treated timber should be labelled accordingly. **Action:**

		SECR to prepare question to **BPC**: is it acceptable to request that this instruction for use/RMM is placed on the label?
7	<u>Harmonized instructions for use for curative/preventive products against dry rot (Serpula lacrymans)</u> DE In order to achieve harmonized product (re)authorisations we propose to agree on a set of instructions for uses with the aim of environmental protection for all products of this type. DE provided a document after the PT 8 EG meeting: **To be discussed:** Does the WG agree on the presented formulations for the harmonized instructions for use (=> see embedded document) and shall these be part of all future authorisations of curative products against *Serpula lacrymans?*	**Conclusion WG-III-2019:** The WG agreed on the presented formulations for the harmonised instructions: • The product shall only be used on areas of masonry that are protected from precipitation. • When treating masonry it must be ensured that the application solution does not contaminate the environment. • The product must not be used on adjacent soil (also cellar floor / natural tamped soil). • No outdoor soil treatment is allowed. • *Only for countries, which require expert knowledge for the person who applies the product:* Application must be conducted by trained professionals only. It was further clarified that although it is relevant for wall/masonry treatment, it is still considered as PT 8 product since the masonry is treated to protect the wood.

9	<u>Variability - leaching from paints plaster and polymers</u> NL Leaching studies are usually not repeated although variation may be expected due to e.g. weather conditions, seasonal variation, and the material tested. The derived endpoints give consequently only a random indication of actual leaching. Considering the expected variation the derived endpoints are only valid for the material tested and only for the test location in case for semi-field studies. Ideally, multiple materials must be tested in laboratory studies and semi-field studies must be conducted at several locations across Europe simultaneously. It should be however realised that especially semi-field studies are laborious and time-consuming. The suggested ideal test design may be therefore inapplicable, but the current test guidelines allows sufficient possibilities to gain more insight in variation with little additional efforts. For example to include both soft- and hardwood in laboratory and semi-field test, and to test three different paints simultaneously. DE and FR provided feedback in the frame of an e-consultation. **To be discussed:** 1. Is it necessary to repeated studies, e.g. with another wood specie, at another location, in another season? 2. How many paints, plasters etc. need to be tested?	**Conclusion WG-III-2019:** No conclusion was drawn but reference was made to the ongoing CEPE study which may provide important information on this topic. The study may be finalised this summer according to CEFIC. **Action**: **SECR** to contact CEPE and check the availability of the study outcome. Item to be scheduled for **AHEE-3**.

10	<u>Usability of tests with film preservatives – which materials should be tested</u> NL A thought starter was provided by NL. FR, FI and DE provided feedback in the frame of an e-consultation. **To be discussed:** The representative material to test for film preservative (PT 7) is a paint or similar thin coating that does not penetrate into the surface below: are studies with materials that penetrate into the surface on which they are applied, such as stain unacceptable to represent intended PT 7 products?	**Conclusion WG-III-2019:** The WG is in line with NL of the opinion that an extrapolation is not possible, however reference was made also to the ongoing CEPE project. **Action**: Item to be taken up provisionally at **AHEE-3** in case the CEPE study shows a result that contradicts the above conclusion.
1b	<u>Related to point 1a, Table 1: Harmonised way to assess the read-across for different products regarding leaching</u> NL	**Conclusion EG:** To be followed up via an e-consultation.
	NL provided a thought starter on read across between data of a specific case. FR, DE and FI provided feedback in the frame of an e-consultation. **To be discussed:** The item relates to a specific case, does NL has sufficient information to proceed with it? Is a general discussion of this specific case of interest/needed at the WG meeting? *[Information deleted since case-specific and therefore confidential]*	**Conclusion WG-III-2019:** NL noted that they received so far sufficient information from the e-consultation; no further discussion is needed at this point in time by the WG meeting. In case further questions come up, they can be asked by **NL** at **AHEE-3**.

Human Health WG-III-2019

Final minutes

18 September 2019

Minutes of Human Health WG-III-2019

21-22 May 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 34 members registered, of which 11 were core members. One stakeholder representative and one stakeholder expert were present. Applicants were registered for their specific substance discussions.

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

2. Administrative issues

SECR informed that:

- According to the Working Procedures (AS and UA), the eCA is responsible for sending the discussion tables and minutes to the Applicant via R4BP3; the WG members were kindly requested to remind also their colleagues in the MSCAs.
- The Rapporteurs are reimbursed by ECHA also for the early WG discussions (for an eCA without a core/alternate member).
- When nominating an advisor to the WG-meetings, a Declaration of Confidentiality of new meeting participant(s) should be sent to SECR.
- In order to ask for registration to the WG-meetings after the deadline, the WG members were kindly asked to contact the SECR by email.

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-II-2019

The minutes were agreed without further changes.

6. Discussion of active substances

6.1 Copper (eCA FR)

The members agreed with the assessment and the substance will move to the BPC. For detailed information, please refer to the minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

6.2 Peroxyoctanoic acid (eCA FR)

The members agreed with the assessment to which the eCA will include some further information. One point remained open and it will be closed in an ad hoc follow-up once the reference specification is established. For detailed information, please refer to the minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

7. Technical and guidance related issues

7.1 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 and is provided in the same format also to the CA meeting.

7.2 HEAdhoc: Applicability of ConsExpo for water-based disinfectants

DE presented a proposal for assessing the exposure to water-based disinfectants with ConsExpo evaporation model. Several questions were raised regarding the scope of the Recommendation and asked to clarify the applicability of the proposal for active substances with significantly lower vapour pressure than that of the solvent. Additional questions were raised on the use of alternative modelling approaches when refinement is needed in the assessment.

The WG members supported the proposal and including the Excel sheet with the calculations for the different proposals as an Appendix to the Recommendation. The WG agreed on the proposal and the document will be published on the HEAdhoc website after revision.

7.3 Applying the read-across assessment framework (RAAF) for biocides

The WG in general supported applying RAAF for biocides, pending clarifications on the impact and the timelines for implementation. The WG also supported the possibility of applying RAAF in the absence of adverse effects, provided that the level of confidence is high and the scientific justification is robust.

SECR will clarify the next steps for the implementation.

7.4 Further guidance on substances of concern

SECR presented the document that was gathering together open questions regarding substances of concern. The intention is to identify as far as possible the questions for which guidance or clarifications are needed, and as the next step, to identify the appropriate bodies to provide the answers. The document will be updated based on the input provided in the different WGs, and will then be provided for commenting in order to identify 1) possible solutions to some of the questions, 2) volunteers to clarify some specific questions and 3) further open questions.

7.5 New TAB entry proposal - Local risk assessment

SECR presented a proposal for a new TAB entry based on an agreement in previous WG in the context of discussion of one Union authorisation case. It was considered that when a product is classified due to a co-formulant, normally a qualitative risk assessment is sufficient unless the co-formulant has a NOAEC value that has been agreed under BPR and that is relevant for the product.

SECR will revise the wording in the proposal and ask the members and ASOs to provide further written comments, since no agreement on the wording could be reached during the meeting.

8. Any other business

8.1 Other information & lessons learned

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

In situ generated active substances

SECR informed of the issues identified for which the need for further guidance has been identified. SECR asked the members and ASOs to identify the highest priority topics and to inform SECR of the willingness to provide drafting.

The issues identified are available in the presentation provided in S-CIRCABC:

- Path: /CircaBC/echa/BPC-WG/Library/Confidential/03. WG - Human Health/Meetings 2019/WG-III-2019/WGIII2019_TOX_8-1_Other info_lessons learned_INFO.pptx
- https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/42ad787c-6e97-4c33-a7cf-843ff4bb65c5/WGIII2019_TOX_8-1_Other%20info_lessons%20learned_INFO.pptx

Action required: members and ASOs are asked to inform SECR of the willingness to provide drafting.

Endocrine disruption (ED)

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

- 4-5 June (confirmed)
- 1-3 October
- 3-5 December

The deadline for confirming the substances for the October ED EG is 31 July 2019. SECR asked the members to confirm the substances by sending an e-mail to ed_eg@echa.europa.eu.

SECR informed that the document *Assessment of ED properties of co-formulants in biocidal products – draft instructions for applicants* has been published[1]. Another document providing instructions for MSCAs has been prepared by BE and FR and was under commenting until 3 June 2019.

Next WG meetings

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

- The WG in July is cancelled
- 18-19 September

8.2 Active substance workshop - Increasing WGs efficiency: 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 and the current lack of submission of the draft CARs.

SECR presented the input and actions suggested in the break-out group that discussed the efficiency of the WGs, as well as the on-going actions that have been launched following the workshop. For details, see the presentation available to MSCAs and ASOs in S-CIRCABC.

[1] https://webgate.ec.europa.eu/s-circabc/sd/d/dc42856d-9209-44bc-8595-b8f5a185664c/CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants.pdf

Annex 1

Human Health WG attendees

Core members
MIKOLAS Jan (CZ)
HOLTHENRICH Dagmar (DE)
ZIKOVA Andrea (DE)
ARAPAKI Niki (EL)
NIKOLOPOULOU Dimitra (EL)
TERUEL Cristina (ES)
LAUMONIER-MAXIMILIEN Elisabeth (FR)
LORI Julia (FR)
BOS Carina (NL)
BRESCIA Susy (UK)
ROBINSON Julie (UK)
KOSHY Lata (UK) - Alternate
Rapporteurs
GOUR Annabelle (FR)
VAILLANT Vincent (FR)
Flexible members
HOELZL Christine (AT)
HERREMANS Yannick (BE)
HOUAMED Anis (BE)
BUEHLER Dominique Anne (CH)
OBERLI Aurelia (CH)
DOLEZELOVA Katsiaryna (CZ)
BOYE PETERSEN Annika (DK)
KÄOSAAR Sandra (EE)
HYVARINEN Tuija (FI)
RYDMAN Elina(FI)
HÄMÄLAINEN Anna-Maija (FI)
PUPIER Cindy (FR)
REY Marion (FR)

BREEN Alan (IE)
GAUSTAD Astrid (NO)
HAUGSTAD Kjetil (NO)
MIDTHAUG Hilde Karin (NO)
ČEBAŠEK Petra (SI)
LESER Vladka (SI)
OLHA Roman (SK)
HOUGH Natalie (UK)
ECHA Staff
AIRAKSINEN Antero (Chair)
DAMSTEN Micaela
MYÖHÄNEN Kirsi
RUGGERI Laura
PAPADAKI Paschalina
ANTAL Diana
ESTEVAN MARTINEZ Carmen
SCHAKIR Yasmin
HONKA Anni
Applicants
Ecolab
SCC
Regcs
Stakeholders
KASURINEN Ossi (CEFIC)
CLARKSCHMID Katherine (CEFIC)
Advisors
PEISER Matthias (DE)
PIEPER Christina (DE)
WEBER Philippe (FR)