Minutes of the Working Group meeting IV in 2018 for Analytical Methods and Physico-Chemical Properties

(Meeting date: 03 July 2018)

18 September 2018

1. Welcome and apologies

The Chair welcomed the participants of the working group meeting which was held as a virtual meeting. No accredited stakeholder organisation (ASO) was present at this meeting.

The chair highlighted that only registered members can participate in this meeting although it is a virtual meeting, hence non-registered persons were requested to leave. 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. Agreement of the agenda

The Chair introduced the draft agenda and no further items were reported to the chair for discussion under any other business (AoB).

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

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

4. Agreement of the draft minutes of working group meetings II 2018

Comments on the draft minutes were received as follows:

Union authorisation of iodine BPF: Denmark

The draft minutes have been 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.

The minutes of the working group meeting II in 2018 have been agreed by the working group members.

5. Outcome of e-consultations

5.1 Commodity Chemicals

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

5.2 Synthetic amorphous silicon dioxide (nano) - post-approval data

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

5.3 Azamethiphos

This item was for information only. The chair explained that an e-consultation was held on post-approval information about the partition coefficient and analytical data for the reference specification. These data and the reference specification have been unanimously accepted. Hence, no discussion at the working group meeting took place.

5.4 Chlorfenapyr reference specification (PT18)

This item was for information only. The chair explained that an e-consultation was held on information about analytical data and the reference specification. These data and the reference specification have been unanimously accepted. Hence, no discussion at the working group meeting took place.

5.5 Peracetic acid – post-approval data

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

6. Discussion of Union Authorisation applications

6.1 Union Authorisation for Novadan biocidal products family containing Iodine/PVP-Iodine - Teat disinfectants

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

7. Any other Business (AoB)

7.1 Active chlorine - data requirements and waiving for Union Authorisation

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

Annex 1 - List of attendees

Country	Members of WG
Belgium	VAN BERLO Boris
Denmark	SKOU CORDUA Birgitte
Estonia	ILMARINEN Kaja
Finland	KARHI Kimmo
Finland	KORKOLAINEN Tapio
France	WEBER Philippe
Germany	MŰHLE Ulrike
Switzerland	AESCHBACHER Michael
The Netherlands	HUIZING Tjaart-Jan
Poland	HUSZAL Sylwester
United Kingdom	BOAZ Louise

ECHA staff
KREBS Bernhard (Chair)
GLANS Lotta
MATTHES Jochen
CIOTA Nadia
HIETANEN Kaisa

Company	Observer
ITW Novadan ApS	KOZIOL Felix
ITW Novadan ApS	LYKKE THOMSON Tine
Peracetic Registration Group	LILLICH Maren

Accredited Stakeholder Organisations (ASOs)	
Organisation	**Observer**
None	---

WG-IV-2018
Final minutes
12.09.2018

Minutes of Efficacy WG-IV-2018

19 July 2018

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 22nd Efficacy WG meeting. There were 4 core and 4 alternate members who participated in the meeting. In addition, 13 flexible members, 1 adviser and 1 ASO representatives (only for the non-confidential agenda items) attended the EFF WG meeting.

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

2. Agreement of the agenda

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

3. 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.

4. Agreement of the draft minutes from WG-II-2018

The Chair informed that comments for the draft minutes of WG-II-2018 had been received from AT, DE and FI. The EFF WG reviewed the amendments made based on the comments and the minutes were agreed.

5. Discussion of Union authorisation applications

5.1 UA for product family containing Iodine/PVP-Iodine (eCA DK)

There were two provisionally closed points concerning efficacy. Since one point concerning co-formulants had not been concluded in the APCP WG, one of these two provisionally closed points was reopened and discussed by the EFF WG. The EFF WG agreed on the role of co-formulants and on the changes required in the meta-SPCs.

7.2 Early WG discussion: Room disinfection – claimed and tested room size (eCA NL)

During the evaluation of UA applications for biocidal products having claims for room disinfection, NL has noticed that the room size to be disinfected varies from rather small to quite big sizes, e.g. food and feed areas. On the request of the eCA, ECHA launched an e-consultation in May 2018, which was commented by several MSs and the discussion on the room size to be tested versus room size claimed was put forward to the EFF WG.

The EFF WG agreed with the proposal of NL, and agreed also that the following sentence concerning mandatory (micro)biological (and chemical, if applicable) validation should be included in the SPC: *"The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room", if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter."*

Since the next Technical Agreements on Biocides (TAB) update will only be due next year, the Chair informed that conclusion on this issue could be uploaded to the newly created, publicly available S-CIRCABC Interest Group: "Documents agreed at BPC WG meetings":

Path: /CircaBC/echa/Documents agreed at BPC WG meetings

https://webgate.ec.europa.eu/s-circabc/w/browse/d02f78aa-983c-4187-9776-c8b5f706511b

6. Technical and guidance related issues

6.1 Update on guidance development (ECHA)

ECHA gave the usual update on guidance development. Currently, the following efficacy guidance documents are under development:

- PT11&12: the first draft version was sent by FR to ECHA few days before the EFF WG-IV-2018 meeting. It will be circulated for comments and discussed in September at WG-V-2018.
- PT19: Drafiting of the PT19 efficacy guidance is in progress. The first two chapters (ants and fruit flies) were already commented by the WG members and will be discussed in September at WG-V-2018.

The WG members were also informed that further amendments of Part B+C are necessary, e.g. update of Appendix 16. DE proposed to check the most conclusive chapters of Part B+C and DE already started the revision. The findings will be sent to the EFF WG members. ECHA kindly asked other WG members to communicate to ECHA any further issues that are noticed.

In addition, any other proposals to update the current version or develop a new guidance should be sent to ECHA by the end of August 2018. All details are available in the working document: *WGIV2018_EFF_6-1_Guidance update*.

7. AOB

7.1 PT 21 antifouling biocidal products (NL)

a) Target organism claims for antifouling paints

Based on the discussion during WG meeting, it was difficult to conclude on the questions prepared by the NL, as only few MSs expressed their opinion. Nevertheless, based on the comments received, NL will prepare a revised version of this document and an e-consultation will be launched to obtain the EFF WG agreement.

Q1: The commenting EFF WG members were rather in favour of the proposal made by the NL, i.e. to have as target organisms: Fouling, Slime, Weed and Animals.

Q2: In the current version of the PT21 efficacy guidance, only macro-fouling is taken into account when efficacy is evaluated. To avoid any confusions at MR stage, the same wording as in the guidance should be used. Also efficacy demonstration against only 'Slime' is doubtful and rather difficult to prove.

Q3: Terms 'hard and soft organisms' were considered a bit confusing, i.e. the EFF WG members were not sure if they relate to animals only or also to other organisms, like e.g. macro algae. Nevertheless, it was underlined that also in this case the current efficacy guidance should be followed, i.e. term 'Animals' should be used.

NL will prepare a revised version based on the comments received and will send it to ECHA. An e-consultation will be launched.

b) Paint layer thickness in static raft tests

The EFF WG members were of the opinion that proposal 1: '*The minimal prescribed (total) paint layer thickness should at least be equal to the paint layer thickness used in the provided efficacy tests. This is necessary to ensure that the paint layer applied by users will remain efficacious during service life of one fouling season (6 months)'* is the preferable option. It was underlined that the layer thickness has a low impact on efficacy. However, the thickness of the layer tested in the efficacy studies should be consistent with the thickness of the layer claimed by the applicant, i.e. the minimum thickness claimed should be the minimum thickness tested. Otherwise, sufficient justification needs to be provided.

The EFF WG members still have the possibility to send written comments to the NL.

7.2 Requirements for simulated use tests in the frame of disinfection of swimming pool (FR) – closed session

The EFF WG agreed with the modified methodology of Phase 2, step1 test. Some alternative of soiling was proposed, as well as clear indication in the PAR concerning active substance concentration measurement.

Regarding monitoring data, the EFF WG was of the opinion that additional information is needed, e.g. concerning organisms tested, parameters measured for microbiological quality. A Newsgroup will be crated on S-CIRCABC as a place for information exchange.

Additionally, potential pass criteria for UBA adapted test for drinking water were proposed by DE to be discussed at the WG in the future.

7.3 Other information (ECHA)

The EFF WG participants were informed about upcoming meetings, deadlines concerning any proposals and working documents for upcoming meeting. The revised template of the Discussion table, including, if applicable, additional section called '*Provisionally closed points*' was presented by ECHA. It was also highlited that the introduction of the active substance/biocidal product is now given by the eCA. ECHA kindly reminded that all communincation related to specific cases, e.g. AS approval and UA applications, should be made *via* R4BP3.

ECHA will send the draft Discussion table (DT) for cross-check to the eCA *via* R4BP3 (using ad hoc communication). The eCAs should use the same way when replying. Important: the access level "Restricted - Authority" must be used when exchanging draft DT between ECHA and the eCA.

All details are available in the working document: *WGIV2018_EFF_7-3_Other information*.

List of Attendees

Efficacy Working Group

Core members
ESCH Daniel (DE)
ATTIG Isabelle (FR)
POULIS Joan (NL)
Alternate members
GUNNEWIG Kathrin (DE)
MAXIMILIEN Yann (FR)
WORM Petra (NL)
SMITH Ryan (UK)
Flexible members
ZUTZ Christoph (AT)
LEPAGE Anne (BE)
A MARCA Maria (CH)
KUNZ Petra (CH)
BAUMGARTNER Rebekka (CH)
PECINKOVA Martina (CZ)
WEINHEIMER Viola (DE)
FONNESBECH VOGEL Birte (DK)
ILMARINEN Kaja (EE)
MCGEE Conor (IE)
BALDASSARRI Lucilla (IT)
DAVIES Michael (UK)
McNEILAGE Sean (UK)

ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
HIETANEN Kaisa
ASOs
David Ashworth – CEFIC
Meredith Theelen - AISE
Applicants
Novadan

Environment WG-IV-2018

Final minutes

22 September 2018

Minutes of Environment WG-IV-2018

5 July 2018

Meetings of the Environmental Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants to the virtual meeting, indicating that there were 31 participants present, of which eight were core members (one represented by alternate) nineteen flexible members and two advisers. Two representative from accredited stakeholder organisation 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. Agreement of the agenda

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

3. 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.

4. Agreement of the draft minutes from WG-I-2018 and WG-II-2018

The minutes were agreed without further changes.

5. Discussion of active substances

5.1 Union Authorisation for product family containing Iodine/PVP-Iodine (eCA DK) – PT 3

There were no open point in the discussion table and no further comments were made at the meeting. The PAR can proceed to the BPC.

5.2 Early WG: Early WG discussion on monochloramines generated in situ (eCAs: AT, FR, SE, UK)

The discussion under this item was foreseen as a thought starter to be followed by an e-consultation and further discussion in an early-WG, as needed. This is the first category of in-situ generated substances assessed under BPR and coherent application of the relevant guidance documents and consistency in the requirements and evaluation among different eCAs is aimed for.

All points remained consequently open and will be followed up by an e-consultation.

Actions:

- **eCAs** to provide relevant documents for the e-consultations
- **WG members/eCAs** to provide additional items to be added in the e-consultation by **13th of July** via the functional mailbox *bpc-environmentalexposure@echa.europa.eu*
- Timelines (for providing the documents for the e-consultation and the e-consultation itself) to be agreed between **eCAs** and **SECR** after the WG meeting.

6. Technical and guidance related issues

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

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

6.2 Proposed corrections in the ESD for PT 6 – Implementation in EUSES (ECHA)

SECR presented the document on proposed corrections in the ESD for PT6. Five points were discussed and SECR proposed a further eight provisionally closed points. The WG agreed with the proposed changes to PT 6 in both the open points and the provisionally closed points and all points but one were closed. One provisionally closed point remained open which will be followed up by SECR post WG (i.e. removal of the input parameter "Emission days" – since it is not used in the calculations).

DE further commented during the WG Meeting that they see the need to adapt also the spraying scenario in table 17 (city scenario):

Current calculation:
City:
Elocalspray,façade,water = 3* (Elocalspray_drift,façade + Elocalrunoff,façade)

Should be modified as:
City:
Elocalspray,façade,water_tier 1 = 3* (Elocalspray_drift,façade_tier1 + Elocalrunoff,façade)

Elocalspray,façade,water_tier2 = 3* (Elocalspray_drift,façade_tier2)

It needs to be checked whether spray drift reaching paved ground leads to an unacceptable risk after a rain event. This is also relevant when a risk mitigation measure to cover the ground is in place.

Therefore DE asked for an update of this calculation also for the spraying scenario in the city.

Actions:

- **SECR** to revise the ESD
- **SECR** to re-check any influence on PEC calculation for the point that remains open
- **SECR** to schedule the agreement of the adaptation proposed by DE for AHEE-2

6.3 Follow up item 7.3g of WG-II-2018 - Proposal for definitions and PEC calculations for wood and other preservatives applied outdoors (NL, ECHA)

SECR and NL presented the document on the follow up on item 7.3g of WG-II-2018 and one point was discussed by the WG. Following the discussion, there was no clear decision on which approach should be taken for the starting point of the PEC calculation (day 0 or endpoint of the previous TIME) as four members were in favour of approach 1 (day 0), three in favour of approach 2 (endpoint of previous TIME), and one WG member in favour of approach 2 with the request to further evaluate how to apply approach 2.

Members in favour of both approaches requested careful evaluation of changing the approach, and respective guidance specifically if changing to approach 2. One member of the WG suggested an impact assessment.

SECR noted that for the time being approach 1 is implemented in EUSES and suggested to further follow up approach 2 in either the next AHEE meeting or in the frame of a leaching workshop. SECR also noted that the two approaches are already used in parallel in practice. Furthermore, changing the approach has an impact on the renewal stage as many CARs applied approach 1.

The point remained open and will be followed up at AHEE-2.

Actions:

- WG members in favour of approach 2 (i.e. FI, DK, CH, NL) to follow up internally if they can contribute to the preparation of recommendations on how to apply approach 2 for discussion at the AHEE meeting and to provide feedback to ECHA.

6.4 Development of guidance for bees (ECHA)

SECR presented the document on the development of guidance for bees. Background for the guidance development was described summarising the reasons why guidance has not so far been considered as a priority and explaining the need to re-initiate the discussion.

DE and CH gave presentations on their national projects where they have started to collect relevant information for the possible bee guidance development. Both DE and CH concluded that there is a need for the guidance development, at least for certain biocide uses. As a first step, it was suggested that harmonised RMMs should be defined. For the more detailed guidance, there is a need to determine the exposure pathways and regarding effect assessment, assessment factors should be defined.

SE, NL, FR, UK, FI and BE provided some initial feedback on the SECR initiative and on the suggested way forward by DE and CH. In general, WG members were happy to see the initiative from DE and CH. However, it was pointed out that before developing the guidance, it should be considered which exposure may happen and which type of scenario there will be no risk to bees, i.e. mapping of potential exposure pathways leading to risk. It was also highlighted that the assessment scheme should be kept simple. Determination of harmonised RMM was supported as the first step in the process.

Regarding the exposure pathways, it was clarified by several MSCA that manure spreading can take place during summer but at the moment there is no knowledge if this could represent a major pathway for exposure to bees.

Some other questions identified for further clarification in terms of the bee guidance included the definition of protection goals, data requirements and systemic vs. non-systemic effects of active substances.

In summary, in short term harmonised RMMs and in the longer term detailed assessment concept for the effect and exposure assessment should be developed.

Actions:

- **SECR** to initiate e-consultation to collect further feedback on the general issue
  - Document for e-consultation: WGIV2018_ENV_6-4
  - Timeline: to be launched in July 2018
- **DE and CH** to initiate e-consultation related to RMMs
  - Document for e-consultation: to be prepared by DE and CH
  - Planned timeline: be started in September 2018

7. AOB

7.1 Other information

Provisional timing of coming WG meetings:
- 18-19 September (AS+UA): WG-V-2018 takes place as physical meeting
- 20-21 November (AS): WG-VI-2018 most likely cancelled since no active substance and so far no requests for early WG meeting
- 3-5 December (UA): WG-VII-2018 provisionally planned, physical meeting under discussion. Back to back with physical AHEE meeting under discussion, depending on availability of items for the AHEE.

Open public CircaBC site: For publication of final WG documents, the date of upload of final documents is the publication date. The side was set up to prevent pending documents awaiting publication e.g. via TAB. It may also contain draft WG documents for information only.
The site is ready for use pending the inclusion of a legal disclaimer:
- Path: /CircaBC/echa/Documents agreed at BPC WG meetings
- Browse url: https://webgate.ec.europa.eu/s-circabc/w/browse/d02f78aa-983c-4187-9776-c8b5f706511b

Recently finalised e-consultations: PT 18 default treatment areas/areas for wet cleaning, SECR to publish in the TAB.
AHEE consultation on the use of PT 18 scenarios for ERA of PT 8, NL to provide summary and conclusion.
EUSES related AHEE e-consultation on PT 1, PT 2, PT 4, SECR to provide summary and conclusion.

Open actions (non-guidance related items):
Agreed at WG-II-2018:
- Item 6.1 (Iodine containing BPF): Further clarification on the update of the classification procedure for the AS (SECR)
- Item 7.5 (Simplification of ERA): Risk envelop approach, SECR to distribute work between volunteers and initiate evaluation (discussion of outcome at AHEE-2?)

Ongoing ENV WG consultations:
- E-consultation on pyrethroid substances (until 12 October 2018)
- Coming soon: AHEE consultation on proposal for environmental risk assessment methodology for treatment of outdoor midges (until 7 September 2018)

PT 21 – CA/CG meeting discussion: CA meeting agreed upon policy lines for harmonized authorisation of antifoulings on vessels (76th meeting)
- *https://circabc.europa.eu/w/browse/dee4a3fa-9b77-461a-a1b3-042f471817b6*
- *https://circabc.europa.eu/d/d/workspace/SpacesStore/dee4a3fa-9b77-461a-a1b3-042f471817b6/CA-Jan18-Doc.7.4.a - Final - Grouping of antifoulings.docx*

Possible need for guidance changes (product authorisation manual)?

Impact assessment on use of the new PT 21 pleasure craft exposure scenarios planned: UK will coordinate based on any MS assessments completed in 2018.

Pyrethroid metabolites - harmonised list of endpoints (LoEP): Next step is the preparation of the harmonised LoEP, eCAs to fill in endpoint information (upload to S-CIRCABC Newsgroup) until 12 Oct 2018.

Relevant impurities: Definition of relevant impurities can be found in Guidance on Information requirements and Guidance on Technical equivalence applications. The current

definition on relevant impurities has been interpreted in different ways, no clear guidance is available.
Initial discussions took place in TOX and ENV WG-III-2017 & WG-IV-2017 and BPC-24 2018; SECR proposes NO change to the current definition, but guidance/clarification how to interpret it.

SECR proposal: Attempt to find a balanced and workable approach between the extremes, FAO and DG SANCO guidance used as a basis:

- FAO plant production and protection paper 228. Manual on development and use of FAO and WHO Specifications for Pesticides. First edition - third revision, 2016. http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Specs/JMPS_Manual_2016/3rd_Amendment_JMPS_Manual.pdf
- DG SANCO (2012) Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009. https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_guidance_equivalence-chem-substances_en.pdf

An impurity is relevant if it fulfils any of the following conditions:

1. It has a **non-threshold mode of action**
2. Its concentration in the active substance equals or exceeds 10% of that triggering **additional/more severe classification**.
3. Its concentration in the active substance equals or exceeds 10% of the concentration that would lead to a 10% **increase in the overall (eco)toxicity of the active substance** (as calculated from e.g. LD_{50}, NOAEL, EC50, NOEC of the a.s.)
4. For impurities of **unknown toxicity**, the **TTC concept** (EFSA 2016) should be used to define cut-off limits and compared to the AEL or other relevant highest reference value of the a.s.

Further steps: Definition of relevant impurities was discussed at the TOX session of WG-III-2018, ENV WG was invited to participate. A commenting period was launched for WGs (Human Health, Environment and APCP) and the BPC members. Deadline for commenting is **7 August 2018.**
Comments from EFSA will also be considered. Following the commenting period, SECR will consider the appropriate follow-up (WG or BPC)

Non-extractable residues: Report on non-extractable residues published on the ECHA website https://www.echa.europa.eu/publications/technical-scientific-reports
The aim of document is:

- improve interpretation of non-extractable residues in the persistence assessment of substances
- review state-of-science on their role in degradation assessment in soil, sediment and water with suspended solids
- to be used as background document for persistence assessment of substances under REACH and BPR.

Endocrine disruptors: ED guidance was published 7 June 2018.
https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation
https://echa.europa.eu/documents/10162/23036412/bpr_guidance_identif_ed_en.pdf
Reminder: for each biocidal active substance

- It is necessary to conclude "*whether the substance should be considered to have ED properties or not to have ED properties*" (CA-March18.Doc.7.3.a- Final)
- Exception: if the eCA proposes clear non-approval, a conclusive ED assessment is not required (agreed at BPC-25)

https://echa.europa.eu/documents/10162/4221979/principles_ed_assessment_in_approval_active_substance_process_en.pdf

Discussion table – new format: No "Introduction", the key information is provided in tabled format. Columns d) and e) were merged, same information is to be included but in one column:

- Earlier: d) Open/closed point, Conclusions; e) Action points, Deadlines
- Now: d) Conclusions and action points

There is a separate table with "Provisionally closed points": SECR proposes to close these points without discussion. They can be raised however by any member at the WG meeting if a discussion is considered as being needed.

7.2 Update on EUSES related activities

SECR provided information on the two ongoing EUSES projects:

EUSES ongoing update (quick fix):

Focus of quick fix is on biocides only, concentrating on an exposure assessment update (release module and fate & distribution modules). The IT technology and user interface as well as "look and feel" remain unchanged. The release of EUSES 2.2.0 is foreseen in Q4 2018/Q1 2019.
SECR thanked to EUSES CG for their support and invited the testing of the EUSES file that are regularly distribute since it is important for finding potential bugs but also to understand whether the design is logical and appropriate.

Out of scope are changes on business content, the implementation follows ESD and spreadsheets and when possible recent decisions from the WG. In addition PT 14 and PT 18 stables and manure storage as well as partially PT 3 (non-availability of final ESD/time limitations). Potential inclusion of these in a future revision.

Current status: the releases module updated concluded for PT 1, 2, 4, 5, 7, 9, 8 and 22. Ongoing are

- PT 10 and 12 releases module update – testing ongoing
- PT 6 and PT 13 releases module update – implementation by contractor ongoing
- PT 8 update of result sheets, inclusion of PEC values direct release – implementation by contractor ongoing

Limitations/ lessons learned: It is important to fully assess consequences of proposed changes to scenarios before approving those changes, e.g. PT 18 Households and professional use – indoor spraying: how to implement wet cleaned areas in the exposure scenario?
The focus of the quick fix was on scientific review of the release module and not on improving the IT implementation as such (no involvement of an IT business analyst!). Potential redundancies where weighted against more clarity, we finally accepted repetitions between life cycles within one PT to increase transparency.

Support is needed for PT 18 households and professional use: How to implement the new default values for the treatment areas and wet cleaned areas per pest in EUSES? A proposed schedule was presented and a request for volunteers were made.

Considerations for the future (major EUSES update):

Stakeholder workshop took place 4-5 June 2018 to present and collect ideas on needs to update EUSES. The workshop report is published at https://echa.europa.eu/-/workshop-on-euses-update-needs.

Main topics of World Café session at the workshop:

- Update of the QSARs models for BCF and Koc
- Man via environment
- Parallel assessment for multi constituent substances and for substances transforming on use or in STP

- Release scenarios and proposal to revisit the current approach for designing the release module
- Update of SimpleTreat
- Sewer Removal/(Bio)Degradation
- Items related to IT implementation

Information collected at the workshop will be used for designing the IT pre study, to be provided to ECHA management for decision whether and how to invest in further EUSES maintenance. The workshop organisation committee will act as expert group to provide input to EHCA.

SECR asked for further volunteers to join the EUSES expert group.

Storage place of workshop related documents for the WG:

- Path: /CircaBC/echa/Ad hoc WG on Environmental Exposure/Newsgroups/EUSES major update/AHEE_ENV WG - Documents for EUSES (major) update Workshop for commenting
- Browse url: https://webgate.ec.europa.eu/s-circabc/w/browse/f1c11ceb-dc1e-4ec6-ae52-8be3a7526613

WG members were invited to share any comments/proposals concerning EUSES in the above Newsgroup.

Appendices:

Appendix 1:

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

Note:

- Issues unchanged since WG-II-2018 are highlighted in grey shading.
- Closed issues are ~~stroke through~~.

1. Guidance related documents

No.	Title (current leader)	Status
1.2	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.
1.3	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)**.
1.4	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. **Discussion in Q4 2018? Legal situation to be clarified.**
1.5	TAB (**ECHA**): Technical Agreements on Biocides	The agreed items from WG-IV-2017 to WG-I-2018 were included in the next TAB version v1.4. **Version 1.4 was distributed for commenting with a deadline for end of May 2018. Comments received to be incorporated, estimated publication: July 2018.** **Alternative solution to publish agreed WG meeting documents is implemented.**
1.7	Evaluation of ESD PT 14 (**DE**)	Shortcomings of the current emission scenario document for rodenticides (ESD PT14) became obvious within the national product authorisation of

[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
		rodenticides. UBA Germany has initiated a research project to review the described scenarios and assumptions. The project is scheduled from January 2016 to November 2017. A commenting round was started on 11th September 2017 with ad deadline for providing comments of 13th October 2017. **Final version including changes following comments from NL was provided by DE. Distribution for written agreement (no further commenting!) after WG-IV-2018.**
1.8	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 for guidance of bees triggered by several referrals discussed at the CG meeting will take place at WG-IV-2018.

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

No.	Title (current leader)	Status
ASSIGEND ITEMS		
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. **Revised version will be provided for discussion/agreement at AHEE-2.**
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** volunteered to take over the item, under preparation (**ready for AHEE-2?**)
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	**NL** volunteered to take over the item. Timing to be defined.

No.	Title (current leader)	Status
	(on-site = 33% / off-site = 67%) realistic? ⇨ *WG-V-2016 – item 6.1*	
2.5	PT 8: Proposal for emission scenarios on how to assess short term antisapstain treatments (**DE**) ⇒ *WG-III-2016 – item 6.7/BPC-17* ⇒ *WG-II-2018 – item 7.3f*	DE took over the item, a thought starter was presented at WG-I-2018 followed by an e-consultation and discussion at WG-II-2018. Final document provided by DE **to be published by SECR**.
2.6	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*	Item taken over by NL (early WG meeting discussion in the frame of an UA case). First discussion at WG-I-2018 followed by an e-consultation and a second discussion at WG-II-2018. **Final document to be provided by NL** for publication by SECR.
2.7	Derivation of a default value for Felim for certain type of substances (**NL**) ⇒ *WG-I-2018 – item 7.6*	Under preparation. To be scheduled for **AHEE-2**.
2.8	Direct emission to surface water – Definition of Tier 2 (**NL**) ⇒ *WG-II-2018 – item 7.2*	NL will start mapping placed of direct release to surface water as preparatory work for a Tier 2 preparation – timeline? (**ready for AHEE-2?**)
2.9	PT 18: Insecticides used in mink farms (**DK**) ⇒ *WG-II-2018 – item 7.3b*	Scenario discussed at WG-II-2018. **DK provided final version, SECR to add to the TAB.**
2.10	PECsediment – direct release to surface water (**NL**) ⇒ *WG-II-2018 – item 7.3c*	Discussion at WG-II-2018, agreement that NL should provide worked examples (under preparation), AHEE to follow up (**ready for AHEE-2?**)
2.11	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 open (**discussion at WG-IV-2018**).
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)		
2.12	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.
2.13	Development of RTU/small scale application scenario for PT 18 (household and professional use) ⇒ *WG-II-2016 – item 6.2*	AHEE member to take over item to be assigned.
2.14	Development of a proposal on how to use Fsim in an	AHEE member to take over item to be assigned.

No.	Title (current leader)	Status
	aggregated exposure assessment for PT 18 ⇒ *WG-II-2016 – item 6.2*	
2.15	Refinement options for PT 11 once through and large recirculating systems ⇒ *WG-II-2016 – item 6.8/6.9*	AHEE member to take over item to be assigned – document form industry awaited.
2.16	PT 21: AHEE consultation - consideration of the PT8 ESD for accumulation and degradation processes (equation 3.11), and the emission pattern for soil exposure (batch-wise vs. continuous release). ⇨ *WG-III-2016 – item 6.4 (AHF)*	SECR to initiate.
2.17	PT 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.
2.18	PT 9: Definition/revision of fixation factors for PT 9 – leather applications ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.19	PT 10: Removal processes ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned. *Note: SECR to check original entry, may be covered already by WGII2018 item 7.3g prepared by NL (OPEN).*
2.20	PT 9: Concentration in soil in PT 9 rubber-roof membrane scenario ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.21	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.
2.22	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.

Human Health WG-IV-2018

Final minutes

18 September 2018

Minutes of Human Health WG-IV-2018

4 July 2018

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 35 members registered, of which 7 were core members. One stakeholder expert was present for non-confidential agenda items. Applicants were registered for their specific substance discussions.

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

2. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. The agenda was agreed without changes.

3. 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.

4. Agreement of draft minutes from WG-II-2018

The minutes were agreed with a minor modification.

5. Discussion of Union authorisation applications

5.1 Union Authorisation for product family containing Iodine/PVP-Iodine (eCA DK)

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

6. Technical and guidance related issues

6.1 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.

6.2 Assessment of liver effects

UK introduced the revised document which consists of a TAB entry and an Annex. An RCOM was prepared which includes replies to the comments received. UK identified two main issues for discussion:

1. The need of enzyme induction data to consider up to 15% liver weight increases as non-adverse/adaptive effects. UK does not consider this necessary as enzyme induction is implicit with liver hypertrophy. Demanding enzyme induction data is considered excessive, but if mechanistic information is available, this should be reported.

2. Proposal to add another 20% value if no liver hypertrophy is seen. UK prefers to only have one value (i.e. 15%) to avoid confusion.

The members generally agreed with the revised UK paper. Several members suggested to slightly reword the sentence related to the NOAEL/LOAEL definition. It was also agreed to clarify in the TAB entry that mechanistic information can include enzyme induction data and to remove the '>10%' value since no proper assessment on adversity (or non-adversity) can be performed when no other information than liver weights is available (e.g. histopathology, clinical chemistry). It was also suggested to add to the TAB entry that the 15% level for relative liver weight increase should not be interpreted as a rigid cut-off limit.

The members in general agreed with both the TAB entry and the annex. However, several members had reservations as to the exact wording of the annex, and SECR noted that the annex was as such not endorsed by the WG. SECR proposed that the TAB entry would be the fully agreed version, while the Annex would be provided as supportive document without full agreement of the WG. UK and some members did not agree, arguing that the Annex is an important guidance document which is essential to correctly interpret the TAB entry. Ideally both documents should be endorsed by the WG. At the minimum, the content of the Annex should be aligned with the revised TAB entry to avoid inconsistencies and diverging interpretations. Other members considered that only the TAB entry is required, without the Annex. SECR was of the view that the annex should be made available to the members, and this could be done either by adding the Annex as background document with a disclaimer indicating that it is not fully endorsed by the WG, or alternatively, it would be possible to continue working on the document and find an agreement on the Annex, noting that this could take a significant amount of time.

The TAB entry was agreed by the WG.

Regarding the Annex, SECR will discuss internally and with UK how best to proceed. In case no further WG discussions are held, the members will be able to comment on the way the information is presented when the next version of the TAB is produced and circulated for commenting.

6.3 Harmonisation of PT 2 exposure scenarios (HEAdhoc)

SECR informed that this document is intended to harmonise the exposure assessments of PT 2 Union Authorisation applications, with the aim of facilitating the peer-review process. This harmonisation approach will be used especially for active substances with high vapour pressure where the inhalation route is the most significant in terms of human exposure.

The members generally supported the document and the approach. Several comments and additional input was proposed to the different scenarios described in the document. The member in charge of developing the document will work together with the SECR in the revision of the document, which will be forwarded to the ad hoc Working Group on Human Exposure (HEAdhoc) for further discussion and agreement.

6.4 Surface Disinfection Model 1 – revision (HEAdhoc)

The SECR presented the document and informed that it had been previously discussed and agreed within HEAdhoc. The use of the β-substitution method for assigning values to points below the limit of detection was the main topic of discussion.

The members supported that considering the specific dataset used in the model development, the β-substitution is an appropriate method to be used in this particular situation. It was agreed that a disclaimer will be included in the document to clarify that this should not be considered as an agreement to always use the β-substitution method in assigning values to <LOD points.

The document was agreed and the relevant part of the document (Appendix 2) will be transferred to the next update of the Biocides Human Health Exposure methodology.

7. Any other business

7.1 Other information & lessons learned

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

New open public CircaBC site

SECR informed that a new CircaBC site has been created for providing the public documents agreed at WG meetings. Draft documents may also be distributed if necessary.

The site will soon be available at:

- Path: /CircaBC/echa/Documents agreed at BPC WG meetings
- https://webgate.ec.europa.eu/s-circabc/w/browse/d02f78aa-983c-4187-9776-c8b5f706511b

WG agenda vs. timing

SECR reminded that the WG agenda is structured according to classes of items (e.g. Active substances, Technical and guidance related issues) and the agenda does not reflect the timing of agenda items.

The timing is affected by a number of constraints and will evolve during the preparatory phase of the meeting. The timing of individual agenda items is normally provided during the week before the WG meeting.

SECR asked the members to inform as early as possible if specific timing is necessary for an agenda item for which the member is responsible for.

Next WG meetings

The timing of the next Human Health WG meetings is provisionally planned as follows:

- 18-19 September 2018 – physical meeting
- 12-22 November 2018 – cancelled or virtual
- 3-5 December 2018 – to be confirmed

Annex 1

Human Health WG attendees

Core members
MIKOLAS Jan (CZ)
SCHUMACHER David (DE)
LAUMONIER-MAXIMILIEN Elisabeth (FR)
LORI Julia (FR)
BOS Carina (NL)
ROBINSON Julie (UK)
BRESCIA Susy (UK)
Rapporteurs
BOYE PETERSEN Annika (DK)
Flexible members
HAUZENBERGER Ingrid (AT)
LEITNER Stephan (AT)
AZZOPARDI Charline (BE)
TORDOIR Charlotte (BE)
HERREMANS Yannick (BE)
ROSSIER Nadine (CH)
ROITZSCH Michael (CH)
ŠUMBEROVÁ Hana (CZ)
THORSEN Charlotte (DK)
HYVARINEN Tuija (FI)
PUPIER Cindy (FR)
BREEN Alan (IE)
FATUR Tanja (SI)
LEŠER Vladka (SI)
DAWICK Hugh (UK)
STEVENS Michelle (UK)

ECHA Staff
AIRAKSINEN Antero (Chair)
ANTAL Diana
DAMSTEN Micaela
ESTEVAN MARTINEZ Carmen
MYÖHÄNEN Kirsi
RUGGERI Laura
CIOATA Nadia
Applicants
SCC
NOVADAN
Stakeholders
COREA Namali (CEFIC)
Advisors
PIEPER Christina (DE)
HANSEN Max (DK)
KIRKEGAARD Maja (DK)
TER BURG Wouter (NL)
GORECKI Roman (PL)