

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

(Meeting date: 16 January 2018)

17 April 2018

### 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 was not allowed.

### 2. Administrative issue

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

### 3. Agreement of the agenda

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

The following items were added to the agenda:

- Alternative co-formulants in biocidal products families
- Radicals generated from hydrogen peroxide

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

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

### 5. Discussion on active substances

### 5.1 2,2-Dibromo-2-cyanoacetamide (DBNPA)

All open issues were discussed.

The reference specification and reference source were agreed.

### 5.2 Active chlorine – generated in situ and bottled – follow-up of WG IV 2017

All open issues were discussed.

The reference specification and reference source were agreed.

### 6. Any other Business (AoB)

### Alternative co-formulants in biocidal products families

The issue refers to biocidal product families which include a high variety of alternative coformulants in the dossier. So clarity was requested on the acceptable variation of alternative co-formulants in a biocidal product family. It was clarified that a working party to the coordination group is dealing with this issue. Therefore it was advised to contact the (national) participant to the working party for further clarification. The APCP working group is not the responsible body for this question.

### · Radicals generated from hydrogen peroxide

Clarification was requested on whether generated hydrogen peroxide radicals are covered by the approval of hydrogen peroxide. The CAR of hydrogen peroxide states that the mode of action is the generation of free radicals from hydrogen peroxide by natural degradation. The competent authority of the United Kingdom received an application for the authorisation of a biocidal product that includes a cold plasma device for generating hydrogen peroxide radicals. The United Kingdom added that the applicant confirmed that radicals are sprayed when the cold plasma device is switched on; in the off mode hydrogen peroxide is sprayed. The question refers to whether this type of application would be covered by the approval of hydrogen peroxide. A similar application was received in France that is still pending. Finland, as eCA of hydrogen peroxide, clarified that this type of application was not included in the application for approval of hydrogen peroxide. No answer could be provided at the meeting whether intentional generated hydrogen peroxide radicals are covered by the approval hydrogen peroxide. Therefore the United Kingdom was advised to provide the question in writing for initiating an e-consultation for clarifying whether this "system" would be covered by the approved hydrogen peroxide or another "system".

**Annex 1 - List of registered Attendees** 

Country	Members of WG
Denmark	Havland Stine
Denmark	SKOU CORDUA Brigitte
Estonia	ILMARINEN Kaja
Finland	KARHI Kimmo
Finland	KORKOLAINEN Tapio
France	WEBER Philippe
France	Six Therese
Germany	MŰHLE Ulrike
Greece	MARAGOU Niki
Italy	CATALDI Lucilla
The Netherlands	POUWELS Marianne
Poland	HUSZAL Sylwester
Slovakia	Mikolaskova Denisa
Slovakia	Banasova Maria
Slovakia	Molnarova Jana
Slovakia	Horská Alexandra
Slovakia	Olha Roman
Slovenia	Čebašek Petra
Switzerland	Aeschbacher Michael
United Kingdom	Boaz Louise

ECHA staff
KREBS Bernhard (Chair)
GLANS Lotta
SCHAKIR Yasmin

Company	Observer
DOW	Buchert Pascale
DOW	McClymont Lynn
Aqualution	Meakin Nicholas
Eurofins	Worthington Mark



WG-I-2018 Final minutes 25.04.2018

# Minutes of Efficacy WG-I-2018 17 January 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 20<sup>th</sup> Efficacy WG meeting. There were 3 core and 4 alternate members who participated in the meeting. In addition, 9 flexible members and 1 rapporteur attended the EFF WG meeting.

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

### 2. Administrative issues

SECR gave a brief information on the administrative issues.

### 3. Agreement of the agenda

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

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

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

### 5. Agreement of the draft minutes from WG-V-2017 and WG-VI-2017

The Chair informed that comments for the draft minutes of WG-V-2017 had been received from AT, DE, FR, IT, SE and two applicants. The draft minutes version was amended in relevant parts and agreed by the EFF WG.

In relation to the draft minutes of WG-VI-2017 no comments had been submitted. The draft minutes version was agreed by the EFF WG.

### 6. Discussion of active substances<sup>1</sup>

### 6.1 DBNPA (eCA DK)

There were no open points in the discussion table. The EFF WG agreed with the evaluation made by the eCA.

### 7. Technical and guidance related issues

### 7.1 Update on guidance development (ECHA)

ECHA gave an usual update on guidance development. All details are available in the working document: WGI2018\_EFF\_7-1\_Guidance update uploaded after the meeting on CIRCABC.

With reference to ongoing update of Volume II, Part B+C (PT5) ECHA proposed to include Appendix 4 being currently published on ECHA EFF WG webpage into the text of this guidance. To agree on the final version of Appendix 4 a virtual workshop will be organised in March 2018, and if agreed it will be moved into the guidance document by corrigendum.

 $<sup>^{1}</sup>$  The details of the substance discussions are considered restricted. Only the non-restricted conclusions are reported here.

### **8. AOB**

### 8.1 Other information & lessons learned (ECHA)

The EFF WG members were informed about upcoming meetings/deadlines, ongoing ad hoc follow-ups and e-consultations. In addition the EFF WG members were invited to send their proposals related to update of the BPR annexes in relation to efficacy part.

The detailed information is provided in the working document:  $WGI2018\_EFF\_8-1\_Other$  info uploaded after the meeting into S-CIRCABC.

### **List of Attendees**

### **Efficacy Working Group**

Core members
GIATROPOULOS Athanasios (EL)
ATTIG Isabelle (FR)
GERRITSEN Lonne (NL)
Alternate members
GUNNEWIG Kathrin (DE)
MAXIMILIEN Yann (FR)
SMITH Ryan (UK)
Flexible members
ZUTZ Christoph (AT)
ILMARINEN KAJA (EE)
NIEMINEN Timo (FI)
RYDMAN Elina (FI)
PECINKOVA Martina (CZ)
BALDASSARI Lucilla (IT)
FONNESBECH VOGEL Birte (DK)
Advisors
DAVIES Michael (UK)
GASZCZYK Malgorzata (PL)

ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
STASKO Jolanta
SCHAKIR Yasmin
Applicants
DOW
Stakeholders
-



Environment WG-I-2018 Final general minutes 8 August 2018

### **Minutes of Environment WG-I-2018**

23 - 25 January 2018 31 January 2018

Meetings of the Environmental Working Group of the Biocidal Products Committee

**Note**: Items 7.2, 7.3, 7.6 and 7.12 on the agenda were followed up in a WebEx meeting on 31 January 2018, the outcome of this WebEx meeting is included in this minutes.

### 1. Welcome and apologies

The Chair welcomed the participants indicating that there were 26 participants present, of which eight were core members (one represented by alternate) and twelve flexible members in addition to three invited experts and two rapporteurs. Two representatives 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. Administrative issues

SECR gave a brief presentation on housekeeping and administrative issues.

### 3. Agreement of the agenda

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

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

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

### 5. Agreement of the draft minutes from WG-V-2017

The minutes were agreed without further changes. The Chair informed that the minutes of WG-VI-2017 will be agreed in a written procedure, to be initiated after the meeting.

### 6. Discussion of active substances

### 6.1 DBNPA (eCA DK) - PT 4

Ten points related to effect/hazard assessment and two points related to the exposure assessment were discussed. All points but two were closed, the two open items will be followed up by an ad hoc follow up.

#### **Actions:**

- Ad hoc follow ups to be initiated by SECR (eCA to prepare the respective background documents).
- **TAB** entry on degradation in the sewer system.
- SECR will look into the QSAR guidance available and assess whether the current ECHA guideline is sufficient and fit for purpose for biocides.

### 6.2 Early WG: exposure assessment for ethylene oxide (eCA NO) - PT 2

The members of the WG discussed a specific approach with regard to the data package and the risk characterisation in PT 2. The WG supported the proposal presented by the eCA.

### 6.3 Glucoprotamin (eCA DE) - PT 2, 4

Three points related to effect/hazard assessment and nine points related to the exposureand risk assessment were discussed. All points were closed.

### 7. Technical and guidance related issues

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

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

### 7.2 Revision of the ESD for PT 14 (DE)

Under the lead of DE, the ESD for PT 14 was revised. New scenarios and sub-scenarios were proposed and some default values have been modified. Guidance on the assessment of local concentrations in groundwater is provided and the risk assessment for primary and secondary poisoning as being proposed in the original ESD for PT 14 and its addendum was revised.

Following a commenting period, remaining open items were collected for discussion at the WG meeting.

At the WG meeting, all but one item noted in the discussion table were closed. The remaining open point will be closed by written procedure. For several points actions were agreed, which are summarised in the following.

### Actions:

- DT point 17: **SECR** to prepare a **TAB entry**, i.e. include table 29 to the TAB, since the values provided there are relevant also for other PTs.
- DT point 18: **DE** to verify if open area scenario indeed represents the worst case.
- DT point 19: **SECR** to coordinate a follow up independent from the ESD for PT 14 on if it is a worst case that FOCUS simulation tools always assume that the application takes place over 26 consecutive years.
- DT point 21 (Ad 3): The question if the agreed AF of 10 is sufficiently conservative to cover interspecies variation should be discussion in the frame of a future revision of Vol. IV Part B (also in relation with other legislations).
- DT point 24: **SECR** to initiate written procedure.

### 7.3 Follow up WG-IV-2017 - item 8.2 (ECHA)

The SECR presented 15 items for discussion related to emission estimations PT 18: one item was remaining from the  $1^{\rm st}$  PT 18 Expert Group (EG) meeting, which covered issues on insecticides applied in stable/manure storage systems; and 14 items were remaining from the  $2^{\rm nd}$  PT 18 EG meeting, which covered issues on insecticides applied in household and professional use.

The majority of the items noted in the discussion table was closed at the meeting or at the follow up WebEx which was held on 31.01.2018. Items 2.3, 2.9 and 2.10 will be followed up in future ENV WG meetings, upon completion of the relevant documents/models by the MS (FR, UK and NL, respectively).

For several points actions were agreed, which are summarised in the following.

### Actions:

- DT point 2.2: **SECR** to confirm with the BPC the validity of the proposed RMM (covering also the question if the legal transfer of the responsibility is acceptable).
- DT point 2.4: **UK** to update their proposal on "Generic treatment areas assigned to each specific pest" including the discussion of the WG meeting on the non-professional users. Afterwards the **SECR** to distribute the document to the ENV WG for written agreement before inclusion in the TAB.
- DT point 2.8: **SECR** to clarify what is meant with "spot application" (i.e. according to the original formulation of the question). Please see the updated DT in the Annex.
- **SECR** to include all agreed items in the **TAB**.

### 7.4 Follow up WG-IV-2017 - item 8.3 (ECHA)

The SECR presented 6 items for discussion related to emission estimations in PT 8 and PT 10. These items were remaining from discussions held at previous WG meetings and/or resulted from follow up e-consultations. The majority of the items was closed. For one point the discussion on the organisation of a leaching workshop was not conclusive. The SECR informed not to have for the time being the resources to organise a WS and DTI noted interest.

For several points actions were agreed, which are summarised in the following.

#### Actions:

- DT point 1: Should the use of the new Time 2 (365 days) be agreed in the future after finalisation of the impact assessment, **ENV WG** to decide on a default value for the case when no leaching study is available (75%?).
- DT point 3: **SECR**: to update the minutes from WG-IV-2017 item 8.3 with the information provided.
- DT point 4: **NL** to finalise the agreed proposal and to provide it to ECHA by the end of February at the latest for discussion/agreement by the WG in a written procedure.
- DT point 5: NL/FR/DK to finalise the agreed proposal and to provide it to ECHA by end of February at the latest for discussion/agreement by the WG in a written procedure.
- DT point 6: Alignment of the ESD for PT 8 with Vol. IV Part B (in regards to the calculation of PEC surface water and PEC sediment) to be taken up in a potential future workshop (e.g. to be added to the leaching workshop).
- SECR to include all agreed items in the TAB.

### 7.5 Open items related to emission estimation (based on thought starters) (ECHA/DE)

Proposals on the following topics were presented by DE for discussion and agreement:

- **7.5 a** PT 3: Item for consideration in PT3 sub scenario 2.3 Disinfection of veterinary hygiene: non-medicinal teat dips
- **7.5 b** PT 4: How to asses private use of disinfectants used in food and feed areas?
- **7.5 c** PT 8: Assessment of anti-sapstain wood-preservatives
- **7.5 d** Need of combined emission assessment for uses of b.p. in domestic premises by non-professional and professional users in PT 18

Most of the items discussed under each of the topics were agreed and closed. For one of the topics (7.5 c) an e-consultation will be launched. For several points actions were agreed, which are summarised in the following.

### Actions:

- On 7.5 b, **Cefic** to provide background information on the area of the treated surface (where a value of 2 m<sup>2</sup> should be used).
- On 7.5 c, **SECR** to launch an e-consultation.
- SECR to include all agreed items in the TAB.

### 7.6 PT 4: Refinement default value Felim (NL)

The WG agreed in principle with the proposal from NL with the following changes:

- A limit Koc value should be defined, below which the proposed value of 0.9 would no longer applied; the agreed Koc value was 400.000 L/kg.
- The applicability is not for ready biodegradable substances but for rapidly reacting substances (abiotic degradation/reaction with organic matter). Applicability to be decided case by case (substance wise).
- The approach considers elimination processes in the food processing plant and covers only Felim, i.e. fraction of substance eliminated due to on-site pre-treatment of the plant waste water.
- It should be clarified for the ESD for PT 4 that the on-site STP is not a full standard STP but covers measures to reduce certain components in the waste water.
- If measurements are available the proposed default values can be replaced by measured data.

The refinement of Felim was further discussed at the follow up WebEx meeting held on the 31 January 2018. NL proposed a way forward to be agreed via written procedure. The WG agreed.

### **Actions:**

- NL to provide a document with the proposal for the definition of the cut-off value of Kow value in addition to the Koc and/or the use of the equations used for PT 13 included in the document presented in point 7.12.
- SECR to launch an e-consultation on the document.
- SECR to prepare a TAB entry.
  - Clarify the equations in the ESD for PT 4 and add clarification to the TAB entry
  - o Both pathways via onsite and offsite STP should be calculated
  - If Felim is used, it should be stated that the eliminating techniques are in place as RMM

### 7.7 Revision of the Addendum for PT 18 (NL)

The NL presented a proposal for revision of the AHEE Recommendation agreed at WG-V-2015 on PT 18: Calculation of PIEC<sub>soil\_grassland</sub> after 10 year. The WG agreed with the revised calculation methods proposed. The actions agreed are summarised in the following.

### Actions:

- **DE** to provide to NL a text proposal to clarify Figure 1 (reflecting only one situation).
- **NL** to revise the Addendum following the WG meeting conclusions.
- **SECR** to prepare **TAB entry**.

## 7.8 Specific items identified in the revision of Vol. IV Part B for WG follow up (ECHA) –

The two agenda items were discussed according to discussion tables.

### 7.8a Triggers for sediment risk assessment for biocides

SECR presented a DT to cover the topic. Some notes from the discussions can be found in the agenda item WGI2018\_ENV\_7.8a The WG decided to keep working on the topic through a dedicated group. SECR will set up a dedicated meeting with CEFIC, UK, DE, FR, NL and ECHA

### Actions:

• SECR to set up a dedicated meeting with CEFIC, UK, DE, FR, NL and ECHA

### 7.8b Relevance of food vs water exposure in sediment toxicity testing

SECR presented a DT to cover the topic. Some notes from the discussions can be found in the agenda item WGI2018\_ENV\_7.8b Finally the WG agreed to set up a dedicated meeting to look again at the topic. SECR will set up a dedicated meeting with DE, FR, UK, NL, SE, CH, CEFIC, ECPA, Centre Ecotox and SECR.

#### Actions:

• **SECR** to to set up a dedicated meeting to look again at the topic. SECR will set up a dedicated meeting with DE, FR, UK, NL, SE, CH, CEFIC, ECPA, Centre Ecotox and SECR.

### 7.9 Simplification of the exposure assessment (all PTs) for biocides (ECHA)

The item as such was not discussed at the meeting but will be followed up at a later meeting. Only one point was taken out of the document, i.e. the change of the mandate of the AHEE.

#### Actions:

• **SECR** to prepare the revised mandates of the AHEE, to be discussed at the next BPC meeting.

### 7.10 Recommendation Fpen

The item was not discussed at the meeting but will be followed up via a written procedure.

#### Actions:

• **SECR** to initiate the written procedure.

## 7.11 Introduction of ENV RAAF (Read across assessment framework) including a worked example (ECHA)

The SECR gave a presentation on the read-across assessment framework (RAAF) including a general introduction to the framework and an example of reporting read-across assessment for a biocidal active substance. An e-consultation will be initiated to collect views from the MSCA regarding the proposed implementation of the ENV RAAF to biocides assessment. The e-consultation will include also commenting of the presented draft template for read-across assessment reporting according to the RAAF principles.

### Actions:

• **SECR** to launch an e-consultation to collect comments and views on the implementation RAAF and the proposed reporting template.

### 7.12 Proposal for a scenario for in-can preservation of fuels in storage tanks - PT 6 (NL)

A preliminary discussion on the proposed scenario by the NL took place at the working group meeting. In general, the WG agreed with the scenario as proposed however, the default values for initial water volume, final water volume, oil volume and fraction eliminated in waste water ( $F_{\text{elim}}$ ) needed additional considerations. Therefore, the WG members agreed to further discussed the document in a WebEx meeting.

At the Follow up WebEx meeting held on the 31 January 2018, NL presented a room document amending the initial default values provided and with additional supporting information. The WG members agreed to give comments in an e-consultation.

#### **Actions:**

• SECR to launch an e-consultation items 7.12 (updated document), including item 7.6

### 8. AOB

### 8.1 Other information & lessons learned

The following **Lessons learned**" were shared:

**General items:** Do not re-open/bring forward items previously agreed by the WG or via an AHF unless there is new guidance or new scientific evidence available justifying a reopening

eCAs were reminded to use accordance check template (to be send together with the CAR to ECHA)

- WG members invited to check first draft agenda: items agreed to be placed on the agenda missing => inform SECR immediately
- SECR to prevent upload of multiple DT versions!
- Applicants to register <u>in time</u> befor the WG Meeting (late requests for registrations will be rejected)

**Items from recent accordance checks:** Additional information requested in the AR for an active substance to be provided at product authorisation stage should be clearly indicated in the PAR. Adapted/new emission scenarios should always be discussed in an early WG discussion – preferably already during the evaluation stage.

The following "Other information" was provided:

The current **naming of WG meetings** (WG-x-201x) will be kept, subsequent numbering independent from AS/UA. Meetings are also not exclusively for AS/UA.

**Update on EUSES quick fix / "big" EUSES update / ESD calculation sheets:** The EUSES quick fix project started (kick-off 16/01/2018). There is a high urgency to finalise/update ESD Excel sheets. SECR need agreed ways forward for all open emission estimation related items. In case of no agreements: the issue will be implemented in EUSES as currently in the ESD calculation sheet.

### 8.2 Update status on Union Authorisations

The item was not presented at the meeting, reference was made to the presentation uploaded to S-CIRCABC.

### **Appendices:**

### **Appendix 1:**

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

### Note:

- Issues unchanged since WG-V-2017 are highlighted in grey shading.
- Closed issues are stroke through.

### 1. Guidance related documents

No.	Title (current leader)	Status
1.2	2 <sub>nd</sub> EU Leaching Workshop for PT	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.
1.2	8 ( <b>ECHA</b> )	<b>SECR</b> opened a Newsgroup on CIRCABC <sup>1</sup> in order to collect the data and perform an impact assessment as soon as sufficient data is available (target: in one year). <b>SECR</b> to include additional time also in the Excel sheet for PT 8 currently under preparation.
	Fish net scenario (ECHA):	
1.3	discussion on the usefulness of the new version of MAMPEC to be initiated	Possible inclusion in MAMPEC discussed with Deltares at AHEE-1, funding to be clarified by SECR (=> potentially in 2018).
		The discussion of the draft guidance is re-scheduled for an electronic procedure, to be started in Q1 2017.
1.4	Guidance on aggregated exposure assessment ( <b>DE</b> )	Documents were provided by DE to ECHA, SECR initiated e-consultation after the WG meeting.
		Discussion in Q1/Q2 2018?
		Version 1.3 was published on the ECHA webpage.
1.5	TAB ( <b>ECHA</b> ): Technical Agreements on Biocides	The agreed items from WG-IV-2017 to WG-I-2018 will be included in the next TAB version (still to be decided if v1.4 or v.1.5, depends on the finalisation date of the APCP part).
		The next TAB version is scheduled to be distributed for commenting mid-February 2018.
1.6	ESD for PT 6 ( <b>DE</b> )	DE has revised the ESD following comments received.

<sup>&</sup>lt;sup>1</sup> **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
		The ESD was endorsed at WG-I-2017, final version from DE is awaited (urgent for EUSES update!).
1.7	Evaluation of ESD PT 14 ( <b>DE</b> )	Shortcomings of the current emission scenario document for rodenticides (ESD PT14) became obvious within the national product authorisation of rodenticides. UBA Germany has initiated a research project to review the described scenarios and assumptions. The project is scheduled from January 2016 to November 2017.  A commenting round was started on 11th September 2017 with ad deadline for providing comments of 13th October 2017.  First discussion at WG-I-2018.

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

No.	Title (current leader)	Status
ASSIG	GEND ITEMS	
2.1	How to use market share data in order to derive a market penetration factor different from default values?  ⇒ WG-I-2015 item 6.2 + WG-II-2015 item 7.3 WG-II-2014 item 6.4 (pulp and paper processing fluids)	A discussion of specific items took place at WG-IV-2015 and at AHEE-1. One item (collection of tonnage data) was discussed at BPC-17 and was forwarded to the 70 <sup>th</sup> CA Meeting, where the collection of tonnage data was not agreed. A summary of the agreed times will be prepared by SECR and provided for information to the ENV-WG at WG-I-2018.
2.2	PT 3: Scenario for disinfection in aquaculture  ⇒ Disinfection project/EMA visit	ECHA contracted out the preparation of a first proposal.  First discussion took place at WG-I-2017, comments received during the commenting period to be added.  Revised version will be provided for discussion/agreement at WG-II-2018.
2.3	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)	<b>DE/UK</b> volunteered to take over the item (update of PBT guidance to be taken into account). Timing to be defined.
2.4	PT 11: Which fraction should be used to calculate the PEC in soil following deposition from air?  ⇒ WG-IV-2016 – item 6.3	<b>NL</b> volunteered to take over the item. Timing to be defined.

No.	Title (current leader)	Status
2.5	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?	<b>NL</b> volunteered to take over the item. Timing to be defined.
	ITEMS (priority indicated in colou tisation based on the time lines pr	rs: high = red, yellow = medium, green = low; rovided in Annex III of the RPR)
2.6	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.
2.7	PT 8: Use of a standard transfer factor (38 or 40) for transferring an application rate per volume to an application rate per surface (leaching rate assuming 100% leaching) or use of a specific transfer factor based on the dimensions of wooden commodity per scenario (of OECD ESD PT 8). $\Rightarrow WG-IV-2015 - item 6.3$	Item was solved in the frame of item 8.3 of the WG-IV-2017, therefore no longer relevant (a factor of 40 was agreed).
2.8	PT 6: Development of an emission scenario for the preservation of unrefined fuels  ⇒ WG-V-2015 – item 7.3	AHEE member to take over item to be assigned.  This item may by send to the ENV WG for an early WG meeting discussion in the frame of an UA case.
2.9	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.
2.10	Development of a proposal on how to use Fsim in an aggregated exposure assessment for PT 18 $\Rightarrow$ WG-II-2016 - item 6.2	AHEE member to take over item to be assigned.
2.11	Refinement options for PT 11 once through and large recirculating systems $\Rightarrow WG-II-2016 - item 6.8/6.9$	AHEE member to take over item to be assigned – document form industry awaited.
2.12	PT 21: AHEE consultation - consideration of the PT8 ESD for accumulation and degradation processes (equation 3.11), and the emission pattern for soil	SECR to initiate.

No.	Title (current leader)	Status
	exposure (batch-wise vs. continuous release).  ⇒ WG-III-2016 – item 6.4 (AHF)	
2.13	PT 8: Proposal for emission scenarios on how to assess short term antisapstain treatments  WG-III-2016 – item 6.7/BPC-17	AHEE member to take over item to be assigned.
2.14	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.
2.15	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.
2.16	PT 10: Removal processes  ⇒ WG-IV-2016 – item 7.3	AHEE member to take over item to be assigned.
2.17	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.
2.18	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.
2.19	PT 19: review of default value for Fsim (worst case to apply the Fsim of PT 18 to PT 19?)  ⇒ BPC-19 - AP 07.05	AHEE member to take over item to be assigned.
2.20	Development of guidance for bees and non-target arthropods   ⇒ CG (2017)	AHEE member to take over item to be assigned.  Note: DE and CH have initiated national projects to collect information which could be the basis for a future guidance document.



Human Health WG-I-2017 Final minutes 24 April 2018

### Minutes of Human Health WG-I-2018

23 - 24 January 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 25 members registered, of which 10 were core members. One stakeholder observer was 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 gave a brief presentation on housekeeping and administrative issues.

### 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 the draft minutes from WG-V-2017 and WG-VI-2017

The minutes were agreed without further changes.

### 6. Discussion of active substances

### 6.1 DBNPA (eCA DK) PT 4

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

### 6.2 Early WG discussion: Amines C10-16-alkyldimethyl, N-oxides (eCA PT) PT 4

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

### 6.3 Early WG discussion: Hydrogen peroxide (eCA FI) PT 11, 12

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

### 7. Discussions on Union authorisations

### 7.1 Early WG discussion: dermal absorption of product family containing Iodine/PVP-Iodine (eCA DK) PT 3

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

### 8. Technical and guidance related issues

### 8.1 Update on guidance development

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

### 8.2 Guidance on dermal absorption (EFSA 2017)

SECR introduced the document, indicating that the January CA meeting agreed on a document provided by ECHA, proposing to replace the CA meeting document *CA-July13-Doc.6.2.b – Final* by an ECHA document that is to be agreed at the BPC. The members were asked for their views on the proposal.

The members supported the document and the approach.

Following a commenting period, the document will be amended and presented for BPC-24 in March 2018.

### 9. Any other business

### 9.1 Other information & lessons learned

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

### Template for reference value information

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

### **Next WG meetings**

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

- 19-30 March: to be confirmed (post-WG note: this meeting is cancelled).
- 23-25 April: exact days to be confirmed likely to be virtual meeting

# Annex 1 Human Health WG attendees

Core members
MIKOLAS Jan (CZ)
NIKOLOPOULU Dimitra (EL)
ARAPAKI Niki (EL)
MAXIMILIEN Elisabeth (FR)
DE SAINT-JORES Jérémy (FR)
BOS Carina (NL)
SCHUMACHER David (DE)
Rapporteurs
BORGES Teresa (PT)
HAVSLAND Stine (DK)
PETERSEN Annika (DK)
Flexible members
BRYS Kristel (BE)
BUEHLER Dominique Anne (CH)
ROSSIER Nadine (CH)
STRAUCH Stefanie (CH)
HÄMÄLÄINEN Anna-Maija (FI)
HYVARINEN Tuija (FI)
RYDMAN Elina (FI)
KARHI Kimmo (FI)
HERRMANN Kristin (DE)
KRAUSE Monika (DE)
PIEPER Christina (DE)
RAY Marion (FR)
LORI Julia (FR)
SUMBEROVA Hana (CZ)
WIWEL Maria (DK)

ECHA Staff
AIRAKSINEN Antero (Chair)
ANTAL Diana
DAMSTEN Micaela
ESTEVAN MARTINEZ Carmen
MYÖHÄNEN Kirsi
PAPADAKI Lina
RUGGERI Laura
SCHAKIR Yasmin
Applicants
ARKEMA
SCC
DOW
DOW Arrow Regulatory
Arrow Regulatory
Arrow Regulatory P&G
Arrow Regulatory P&G Stakeholders
Arrow Regulatory P&G  Stakeholders WIETOR Jean-Luc (CEFIC - EBPF)