Minutes of the Working Group meeting V in 2019

Analytical Methods and Physico-Chemical Properties

(Meeting date: 12/13 November 2019)

24 March 2020

1. Welcome and apologies

The Chair welcomed the participants of the working group meeting. A representative of CEFIC was present at the meeting as an accredited stakeholder organisation (ASO).

Participants of the working group were informed that the meeting is recorded, but solely for drafting the minutes and 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 for information by ECHA.

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). No further items were added to the agenda.

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 IV 2019

The working group members had no comments on the draft minutes during the commenting period. Minor changes were requested and agreed by the working group members at the meeting.

Thereafter, the minutes of the working group meeting IV in 2019 were agreed by the working group members.

6. Outcome of e-consultation and discussion

The outcome of e-consultations were presented to the working group members and discussed if needed.

7. Discussion of active substances

7.1. Glyoxal PT 02, 03, 04 – eCA: FR

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

7.2. Peroxyoctanoic acid PT 02, 03, 04 – eCA: FR

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

8. Discussions of Union Authorisations

8.1. UA for product family containing hydrogen peroxide – eCA: LV

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

8.2. UA for product family containing propan-2-ol – eCA: DE

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

8.3 UA for product family containing CMIT/MIT– eCA: FR

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

8.4 UA for product family containing peracetic acid – eCA: UK

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

8.5 UA for product family containing hydrogen peroxide – eCA: UK

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

Annex 1 - List of attendees

Country	Members of WG
Switzerland	Aeschbacher Michael
Germany	Mühle Ulrike
Germany	Schulte Petra
Estonia	Ilmarinen Kaja
Greece	Maragkou Niki
Greece	Tzanetou Evangelia
Finland	Karppanen Essi
Finland	Vuorensola Katariina
France	Ali Shanez
France	Aubin Aurelie
France	Boitier Caroline
France	Bujard Thomas
France	GOUR Annabelle
France	Lebee Clement
France	Six Therese
France	Weber Philippe
Italy	Cataldi Lucilla
Latvia	Igaune Ieva
The Netherlands	Huizing Tjaart-Jan
Norway	Helgerud Trygve
Norway	Stave Sekkenes Marianne
Poland	Huszał Sylwester
Sweden	Alpe Mia
Slovenia	Čebašek Petra
Slovenia	Velikonja Bolta Špela
United Kingdom	Boaz Louise
United Kingdom	Bourne Richard

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

Company	Agenda item	Observer
Schuelke & Mayr GmbH	8.2 - UA containing propan-2-ol	Steigleder Esther
Schuelke & Mayr GmbH	8.2 - UA containing propan-2-ol	Breuer Franziska
BASF SE	7.1 - Glyoxal	Weiskopf Verena
BASF SE	7.1 - Glyoxal	Hazenkamp Menno

Contec Cleanroom (UK) Ltd	8.4 – UA containing peracetic acid 8.5 - UA containinghydrogen peroxide	Murphy Siobhan
Ecolab Deutschland GmbH	8.1 -UA containing hydrogen peroxide	Geering Christopher
Ecolab Deutschland GmbH	8.1 - UA containing hydrogen peroxide	Forth Peter
Ecolab Deutschland GmbH	7.2 - Peroxyoctanoic acid	Gräf Helena
Ecolab Deutschland GmbH	7.2 - Peroxyoctanoic acid	Koziol Felix

Accredited Stakeholder Organisations (ASOs)	
Organisation	**Observer**
CEFIC	Van Berlo Boris

WG-V-2019
Final minutes
31 March 2020

Minutes of Efficacy WG-V-2019

12-14 November 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 30th Efficacy WG meeting. There were 7 core members, 3 alternate members, 14 flexible members and 1 adviser who participated in the meeting. In addition 4 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 brief information on the administrative issues.

3. Agreement of the agenda

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

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

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

5. Minutes

DE and NL had sent comments on the EFF WG-IV-2019 draft minutes. The revised minutes were agreed at the meeting.

6. Discussion of Union Authorisations

6.1 UA for product containing propan-2-ol (eCA DE)

There were four open points and one provisionally closed point for discussion, and all points were closed at the meeting. Please refer to the confidential minutes in the form of the discussion table for more details.

6.2 UA for product family containing CMIT/MIT (eCA FR)

There were five open points for discussion, all points were closed at the meeting. Please refer to the confidential minutes in the form of the discussion table for more details.

6.3 UA for product family containing Peracetic acid (eCA UK)

There were three open points for discussion, all points were closed at the meeting. Please refer to the confidential minutes in the form of the discussion table for more details.

6.4 UA for product family containing Hydrogen peroxide (eCA UK)

There were four open points for discussion, of which three were closed at the meeting. For one point an ad hoc follow-up will be launched. Please refer to the confidential minutes in the form of the discussion table for more details.

6.5 Early WG of general interest (eCA BE)

Please refer to the confidential minutes in the form of the discussion table for more details.

6.6 Early WG of general interest (eCA BE)

Please refer to the confidential minutes in the form of the discussion table for more details.

7. Discussion of active substances

7.1 Glyoxal (eCA FR)

There were no open points for discussion. The EFF WG agreed with the evaluation of the eCA.

7.2 Early WG of general interest (eCA DE)

Please refer to the confidential minutes in the form of the discussion table for more details.

7.3 Early WG of general interest (eCA DK)

Please refer to the confidential minutes in the form of the discussion table for more details.

7.4 Early WG of general interest (eCA IT)

Please refer to the confidential minutes in the form of the discussion table for more details.

8. Technical and guidance related issues

8.1. Vol. II, Parts B+C – PT19

Three chapters to be included in the future PT19 guidance, i.e. Mosquitoes, Biting midges and Ants were discussed during the meeting.

In addition, results from the validation of arm-in-cage (AIC) tests performed by three different institutes were presented by Cefic/AISE. The obtained data were analysed by an external statistician both per institute and by combining all three institutes. The statistical analysis focused on:

- Comparing results among the institutes – the combined results showed that there are significant differences related to different parameters between the laboratories. When a pairwise comparison was made some correlations were found.
- Impact of the number of mosquitoes on landing pressure:
    - with sleeves – there were no significant differences when comparing the mean landing pressure with the number of mosquitos,
    - without sleeves – a significant difference was shown.

  The results showed that the number of mosquitoes is an important and more relevant parameter than density. It was proposed to define the minimum and maximum landing pressure used in the test and to recommend minimum and maximum number of mosquitoes per cage. Moreover, the sleeves mitigate the differences between number of mosquitoes and landing pressure, which may reduce the deviation between replicates.
- Impact of the AIC test design (with vs without sleeve) on landing pressure and Complete Protection Time (CPT)
    - landing pressure – much higher in case the test is performed without sleeve, the use of sleeve also minimised the differences between laboratories
    - CPT – the results differed between laboratories, when analysing the results obtained by each laboratory without sleeve. CPT was longer in tests performed with sleeves and the differences between laboratories decreased.
- Landing pressure in AIC test compared to field test – all field tests were performed in Italy, in highly infested sites, with *A. albopictus.* Based on the results the worst case (20-30 landings/min. which corresponds to 100-150 landings/5 min. of exposure) had

been chosen, and should be followed in the laboratory tests. It corresponds to number of landings in the AIC tests with sleeve. IND proposed to adopt a minimum and maximum landing pressure.

- Impact of the dose on CPT – all results shows that the dosage (0.5 g/600 cm^2 vs 1 g/600 cm^2) impacts CPT. IND is of the opinion that the lower dose should be used, however it will significantly reduce the CPT. Therefore, it was recommended by IND to reconsider the definition of the CPT.

The EFF WG members agreed that the landing pressure is a more appropriate parameter than the density or the number of mosquitoes, however the range proposed by IND was considered to be a bit too narrow. It was pointed out that it is important to set up the appropriate minimum level, as the maximum is rather a recommendation.

With relation to the test design (with or without sleeve) the opinions of the EFF WG members differed. It was proposed to recommend the sleeves, but not to reject tests without sleeve.

The main concern was raised in relation to the tested *A. albopictus*. The EFF WG was of the opinion that more species should be tested. IND proposed to compile available results obtained with *Culex* spp. or *Anopheles* spp. and share these data with the EFF WG. The EFF WG members are invited to contact other experts or the applicants and cross-check if any data with *Culex* spp. or *Anopheles* spp. landing pressure are available, and share this information with ECHA in order to launch an e-consultation before the next discussion at EFF WG-I-2020.

Cefic/AISE will conduct the room test with a minimum of 20 landings/min. as accepted by the EFF WG.

The discussed chapters, i.e. Biting midges and Mosquitoes will be revised by the leading . Chapter related to Ants was finalised during this meeting and is ready for PEG discussion, which will take place possibly in Q4 2020.

8.2. Vol. II, Parts B+C – PT11 (FR)

The draft guidance has been previously discussed at EFF WGs V-2018 and II-2019. Additionally a trilateral meeting was organised 10 September 2019 by Anses with FR, Cefic-EBPF and ECHA representatives, to clarify/obtain some concrete proposals from Cefic-EBPF on the issues raised by them.

In addition to the guidance document claims matrix drafts were discussed at WG-I-2017, where several borderline claims were identified as requiring COM/CA consultation. Cefic informed that a position paper regarding scope-related issues prepared by Cefic-EBPF was sent to MSs for commenting after the discussion at 85th CA meeting in September. Based on the comments received, Cefic is currently preparing a revised version, which will be submitted for a second CA discussion beginning next year.

The structuring of use categories was discussed, especially whether the category "closed cooling systems and liquids in closed/open heating" (chapter 2.2.1.3) could be combined with closed cooling systems, as well as the addition of smaller-scale and less common uses. It was agreed, for the time being, to leave the structure and naming as it is (see below), and amend it later, if appropriate.

1) Preservation of cooling systems

   - Once-through cooling systems
   - Open recirculating cooling systems
   - Closed systems

2) Preservation of processing liquids

   2.2.1.1. Air conditioning and air washer with drift eliminators/scrubbers/humidifier systems

2.2.1.2. Pasteurisers, sterilisers, wash waters and conveyor lubricants

2.2.1.3. Liquids used in closed/open recirculating heating and associated pipework

2.2.5.1. Preservation of in-use wood treatment solution

FR presented the results of the e-consultation from July-August 2019 related to the requirement to show growth in the untreated control and to the required pass criteria for the treated samples. The majority of the respondents agreed that growth in the control should be required for preservatives, or it should be shown that the matrix is degraded by the target organisms. MSs and Cefic-EBPF agreed that contact time is not relevant for preventive treatment, and should not be mentioned in the SPC. Regarding criteria for demonstrating curative action, the views differed on whether growth should be shown prior to the addition of the biocide in the treated sample.

The proposal to require two efficacy tests for preventive treatment, standard ASTM E645 and in addition a modified ASTM E645 or IBRG FFG19/006/1 to show growth in the control, was discussed intensively. The EFF WG agreed that only one test should be required, which can be either modified ASTM E645 or IBRG FFG 19/006/1. Growth in the control should be shown; in the case of ASTM E645 it can be established with a lowered inoculum, adding yeast extract, and increasing incubation time from 24 h (at least for fungi). If it is not possible to demonstrate microbial growth in the control, but degradation of the matrix in question is a relevant issue and is demonstrated, that can in well justified cases also be considered sufficient.

It was agreed to amend the composition of synthetic cooling water given in the draft guidance according to proposal from Cefic-EBPF (changing pH into 8 ± 0.2, removing value for conductivity, amending the description of organic soiling to reach the intended TOC value). It was also clarified that the synthetic water composition given in the IBRG FFG 19/006/01 serves as an example which has been taken from EN 13623 (Buffered Ferrous Hard Water for treatment of cooling water, BFHW), and other compositions can be used, if appropriate. Also water from field sites can be used instead of synthetic water, when the chemical parameters of the water are described.

Regarding the requirement to show growth in the control prior to curative treatment it was agreed that growth does not need to be shown, as long as the initial contamination is sufficient to enable demonstration of the required log reduction.

Also some other issues were agreed upon. Hydraulic retention time was amended into hydraulic holding time, along with a footnote indicating that the holding time index (HTI), i.e. the time in which a solute in the cooling water decreases into 50% in concentration, is 0.693 x V / BD, where V is volume of the system and BD is blowdown rate. For a claim against mycobacteria *M. chelonae* and *M. abscessus* will be added as examples of test species, but also other *Mycobacterium* spp. can be used when justified. For a general claim against algae both cyanobacteria and (green) algae should be tested as a consortium, but both can also be claimed separately. For amoeba also other *Naegleria* spp. besides *Naegleria lovaniensis* can be accepted as a test organism. In the case of amoeba, it was also agreed that a laboratory simulated use test can be accepted instead of field monitoring data. For *Legionella* the same efficacy criteria as for other bacteria will be introduced for preventive treatment; nevertheless national requirements should also be considered. Expression of pass criteria as log reductions was preferred over percentages.

It was also agreed that the statistical requirements set for preservatives in BPR Vol II, Parts B+C efficacy guidance should be followed.

Action points:

- Cefic-EBPF will make a proposal for definitions of offline and online treatments and for rephrasing chapter 2.1.3. (EBPF comment number 19);
- AT will make a proposal for a simulated use test against amoeba (chapter 2.1.4.1; EBPF comment no 33);
- DE will make a proposal for revised text for testing times in preventive efficacy tests (sections on test conditions).

All proposals need to be sent to FR by the end of 2019.

8.3. Application of the tiered approach to preservatives evaluation (DE)

DE presented the issue. The first question was which studies are required for product authorisation (part A). The EFF WG agreed that when appropriate Tier 2 studies are submitted, no Tier 1 studies need to be submitted for authorisation of preservative biocidal products. If Tier 3 studies are submitted, additional laboratory evidence (Tier 1 or Tier 2) needs to be submitted, unless justified why it is not possible to mimic relevant use conditions in a laboratory setting.

The second question, what are the basic factors for Tier 2 studies, was discussed along with the ageing examples presented in the document (part B). It was pointed out that for PT 11 and PT 12 it has been agreed that a tiered approach will not be followed. The EFF WG was of the opinion that the part discouraging tests on agar plates and using nutrient media needs to be clarified. In general the EFF WG, however, agreed with part B.

Action point: DE will prepare a proposal for a TAB entry and send it to ECHA.

8.4. P2S2 tests required to support fungicidal and virucidal claims of hard surface disinfectants for applications with mechanical action (FI)

The EFF WG agreed that as long as suitable Phase 2 step 2 tests are not available, Phase 2 step 1 tests are sufficient to show virucidal, fungicidal or sporicidal activity in cases where EN 16615 test is used to demonstrate bactericidal or yeasticidal activity. DE disagreed and considered that non-mechanical Phase 2 step 2 tests should be performed when those are available and tests with mechanical action are not.

9. AOB

9.1. Introducing the Activities Coordination Tool (ACT)

ECHA gave a presentation and demo of ACT. The presentation is available in S-CIRCABC.

9.2. Other information & lessons learned

All details are in the working document: *WGV2019_EFF_9-2_Other info&lessons learned* available in S-CIRCABC.

In addition DE presented a room document related to an e-consultation on feasibility of field tests for Legionella claims (PT 4). DE questioned whether it is reasonable to request field test for *'PT 4 surfaces in human drinking water systems'* in the Vol II, Parts B+C efficacy guidance since it turns out to be very difficult to get access to infested sites to perform efficacy tests. Therefore, DE suggested that a simulated use test may be an appropriate alternative to a field test. The EFF WG agreed with DE proposal that applicants should submit a quantitative suspension test and in addition either a field test or a simulated use test for *Legionella* claims. To make it publicly available DE will prepare a document, which will be posted on publicly available part of CIRCABC for the time being and in the future the Vol. II, Parts B+C, including Appendix 4, will be revised in this respect.

List of Attendees

Efficacy Working Group

Core members
ATTIG Isabelle (FR)
DUH Darja (SI)
GIATROPOULOS Athanasios (EL)
HAMEL Darka (HR)
JANSEN Irina – alternate (DE)
MARCU Horatiu (RO)
MAXIMILIEN Yann - alternate (FR)
SMITH Ryan (UK)
WORM Petra – alternate (NL)
ZUTZ Christoph (AT)
Flexible members
BALDASSARRI Lucilla (IT)
BLODÖRN Krister (SE)
CLEYTON JØRGENSEN Charlotte (DK)
FISCHER Juliane (DE)
FRANK Ulrike (SE)
GURBA Alexandre (CH)
JUSZCZUK Marek (PL)
KAUKONIEMI Sanna (FI)
KRÜGER Martin (DE)
LEPAGE Anne (BE)
McGEE Conor (IE)
NIEMINEN Timo (FI)
PECINKOVA Martina (CZ)
PEELMAN Natania (BE)
ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
RAULIO Mari
HONKA Anni
Applicants
Dupont
Contec
Advisors
ANDRIESSEN Rob (NL)
Stakeholders
KASURINEN Ossi (CEFIC)
LOPEZ SERRANO Paloma (CEFIC expert)
MORENO Mara (AISE expert)
VAN SLOUN Petra (CEFIC expert)

Environment WG-V-2019

Final minutes

31 March 2020

Minutes of Environment WG-V-2019

14-15 November 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 23 participants present, of which 6 were core members, thirteen flexible members, two rapporteurs and one adviser. One representatives from accredited stakeholder organisation was present at some agenda items. Applicants were registered for their specific substance discussions.

Participants were further informed that the meeting would be recorded solely for the purposes of writing the minutes and that this recording would be destroyed after the agreement of the minutes.

2. Administrative issues

SECR gave a brief presentation on administrative issues.

3. Agreement of the agenda

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

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

The Chair invited all members to declare any potential conflicts of interest in relation to the agreed agenda. None was declared. The chair declared an interest in one of the cases which however were not considered as conflict of interest.

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

The minutes were agreed without further discussion.

6. Discussion of Union Authorisation cases

6.1 UA for product family containing propan-2-ol (DE)

One point was discussed related to the assessment of ED properties of the co-formulants. Several comments were raised in regards to the high workload associated with the assessment of ED properties of non-active ingredients. One of the members highlighted that in some cases there could be up to 100 co-formulants.

Actions:

- The eCA will update the assessment to include the elements highlighted by different members including the details of the assessment.

6.2 UA for product family containing CMIT/MIT (FR)

Three points were discussed for this case. One of the points was related to the assessment of ED properties of the co-formulants. Similar comments were raised to point 6.1. Another point was related to the exposure calculations and which are the values that should be used. The last point was related to the need for RMM and exposure assessment via municipal STP.

Actions:

- The eCA together with ECHA will consider how to best word it [agreed water content in the tank, maximum size of tank] in the opinion and decide whether it should be in the instructions for use or as a RMM or just as part of the risk assessment.
- ECHA will follow up with NL for the finalisation of the emission scenario for in-can preservation of fuels in storage tanks (PT06) in regards to the STP settings. The ECHA will also highlight the need to address the stage of the process in which the product is used and specify different sizes of the tanks in the ESD.
- The eCA will check whether the 2nd RMM is needed and where it should be placed in the PAR and Opinion

6.3 UA for product family containing Peracetic acid (UK)

There was only one point for discussion related to classification. The WG agreed with the proposed classification provided by the eCA.

Actions:
- No actions were identified

6.4 UA for product family containing Hydrogen peroxide (UK)

There were no open points for under this agenda item.

Actions:
- No actions were identified

7. Discussion on active substances

7.1 Glyoxal (FR)

Three points were discussed: one point related to the assessment of endocrine disrupting properties, another point related to exposure and a last point related to the possibilities to refine the assessment of groundwater concentrations. The later was for discussion only, not for agreement.

The point on exposure was closed and the one on ED remained open and will be followed up via an ad hoc follow up.

Actions:
- The **eCA** will amend the assessment and conclusions on ED for non-target organisms to include all the lines of evidence that have been discussed during the meeting. Once the assessment has been revised the **SECR** will launch an ad hoc follow up and include DE, SE, UK, NL, CH, ES, AT, FI, IE, ECHA and the Applicant. All rest of members for information.
- The **SECR** will include in the TAB the following scenario agreed at the meeting:

  Disinfection dipping scenario for PT 4 medium to small scale applications:

Variable/parameter	**Symbol**	**Value**	**Unit**	**Origin**
Input				
Concentration of active substance in the dipping bath	Cform		g/L	S
Volume of solution in a dipping bath	Vbath	100	L	D
Number of sites using the disinfection solution connected to the same STP	Nappl	5	[-]	D
Fraction of substance disintegrated during or after application (before release to the sewage system)	Fdis	0	[-]	D (ESD PT 4)

Fraction of substance eliminated due to onsite pre-treatment of waste water	Felim	0	[-]	D (ESD PT 4)
Fraction released to waste water	Fwater	1	[-]	D (ESD PT 4)
Output				
Local emission to waste water	Elocalwater		kg/d	O
Calculation Elocalwater = Cform x Vbath x Nappl x (1-Fdis) x (1-Felim) x Fwater				

7.2 New endpoints for PBO (EL)

This agenda item involved the discussion of certain mistakes and further corrections made to the CAR which had been identified after the active substance approval. In addition, new data had been made available by the applicant and had been evaluated by the Greek MSCA. ECHA clarified that at this stage only corrections to the error should be done and new guidance should not be applied and previous agreements should not be re-opened. The WG agreed to the corrections performed.

In relation to the new data generated after active substance approval the WG agreed with the assessment performed by the applicant.

DE raised some comments in regards to the organic matter corrections for soil and sediment organisms and highlighted that Vol IV Part B may be unclear. Therefore DE agreed to prepare a discussion paper on the issue.

Four discussion points were discussed.

Actions:
- **DE** would like to consult the WG on how to perform and under what conditions should OC normalisation be done.
- **NL** to send the concrete proposal to DE on the use of Foc (Suspended matter) vs Foc (sediment).

7.3 Bardap 26 – PT 8 (P and T assessment) (IT)

The applicant had generated further information to confirm the P and T status as requested under section 2.5 of the opinion. This item had been discussed previously through a WebEx meeting in June 2019 where some comments were collected (please refer to the minutes from WGIII2019). After the WebEx, additional data was provided by DE and the Applicant and a re-assessment by the eCA was presented.

The WG generally agreed with the assessment and agreed that the substance is not T and not P for soil and sediment. The WG agreed that Bardap 26 is not meeting the P criterion for water although some members had reservations on this conclusion. Both arguments (in favour of arguing the substance is not P and that the information is insufficient to conclude on the P status) will be mentioned in the CAR. Since the substance is not T and not B, the WG agreed not to continue with the P assessment for the water compartment.

Actions:
- No actions were identified

7.4 New endpoints for Dinotefuran (NL)

In the frame of applications for national authorisation of dinotefuran-containing products, the Dutch CA received a number of studies on the active substance dinotefuran, which were not included in the CAR of dinotefuran (PT18). The NL CA evaluated the new studies and updated the PNEC value for soil as well as information on degradation in the aquatic compartment (DT50 values and persistence criterion).

Actions:
- No actions were identified

8. Technical and guidance related issues

8.1 Overview on guidance (SECR)

SECR informed of the CA meeting document regarding guidance prioritisation drafted by ECHA for the CA meeting in November. SECR noted that the document contains a list of highest guidance priorities for 2020-2021 which is likely to fully bind ECHA's resources on guidance and may influence progress on other guidance topics as well as other activities.

With regard to future activities on guidance for bees for biocides while COM is raising a need to carry out a feasibility study for such a guidance, FR, SE, DE, AT, NL, IE and FI confirmed that there is a need for guidance on bees for biocides. Initially, several members have indicated interest in supporting this guidance development. It was agreed that MS would confirm to ECHA after the meeting if they would have resources available to support activities on this guidance development for biocides as well as indications if such experts have potentially any experience with EFSA guidance on bees. CEFIC noted that they would like to participate even taking part in the drafting

Furthermore, as a standard agenda point SECR presented the status on guidance development, issues identified for the AHEE and e-consultations. No updates from WG members during the meeting have been made.

Actions:
- **ECHA** to consult the member states on their potential contribution to the development of guidance for bees and other non-target arthropods during 2020-2021.

9. AOB

9.1 Other information & lessons learned (SECR)

SECR made a presentation on this agenda item including also some slides for agenda items 9.2 and 9.3. A few notes from the presentation:

- In relation to read-across assessment framework SECR informed that a document will be brought for agreement at the next BPC (Dec 2019) on the use of RAAF in biocides assessment. SECR informed that a report template for read-across assessment has been prepared.
- In regards to Pyrethroid metabolites and harmonised LoEP the SECR provided an update on the progress. Second WG review and commenting by the applicants is expected end of 2019 – beginning 2020. Another discussion at WG is foreseen in March 2020 and at BPC in June 2020.
- Provisional dates for the ED-EG were presented.

- The document on interpreting the definition of relevant impurities was agreed at BPC-31 (June 2019). The agreement applies for active substances submitted after 24 December 2019
- SECR reminded about the active substance action plan that was presented at the 88th CA meeting

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

9.2 Update on EUSES (SECR)

SECR provided updates on the topic under 9.1

9.3 BPC document on Interpreting the definition of relevant impurities – impacts on ENV assessment (SECR)

SECR provided updates on the topic under 9.1

9.4 Development of the bioaccumulation assessment for air-breathing organisms: use of mammalian toxicokinetic data in bioaccumulation assessment – project update (SECR)

The SECR made a presentation on the project. ECHA will inform back on the developments.

9.5 Training on assessing endocrine activity using in vitro methods (SECR)

SECR gave a presentation on how in vitro methods can provide important information for the ED assessment. The presentation provided an overview of the different types of assays that can be frequently encountered in the scientific literature. It explained the basics on how they work and what type of information they can provide. Specific attention was also given to the in vitro assays from the US EPA ToxCast program, its derived models and its relationship to the US Endocrine Disruptor Screening Program. The results of the assays were put into context by linking them the specific events in Adverse Outcome Pathways, which are available in the AOP Wiki. The overall feedback was very positive, and several members asked whether there could be some more training on this topic in the future.

Appendices:

Appendix 1: List of participants

Core members:

- (DE) Daniel **FREIN** - rapporteur
- (FR) Stéphanie **ALEXANDRE** - rapporteur
- (IE) Helena **JOYCE**
- (NL) Karlijn **HOLTHAUS – alternate member** - rapporteur
- (SI) Petra **MURI**
- (UK) Neil **HARPER** - rapporteur

Flexible members:

- Kantner Christian (AT)
- Leroy Celine (BE)
- Lefebvre Frederic (BE)
- Gyalpo Tenzing (CH)
- Michaelis Katja (DE)
- Stang Christoph (DE)
- Sulg Helen (EE)
- Martín Vallejo Myriam (ES)
- Kaukoniemi Sanna (FI)
- Pasanen Jaana (FI)
- Podlaska Agnieszka (PL)
- Boqvist Pernilla (SE)
- Molnarova Jana (SK)

Rapporteurs :

- Paxinou Akrivi-Chara (EL)
- Orru Maria Antonietta (IT)

Member's advisor:

- Larno Valérie (FR)

ASOs:

- Ossi Kasurinen (CEFIC representative) – all agenda items except closed ones

Human Health WG-V-2019

Final minutes

24 March 2020

Minutes of Human Health WG-V-2019

18-19 November 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 30 members registered, of which 8 were (alternate) core members. One stakeholder representative was registered. Applicants were registered for their specific substance/product 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 of an online Interact training taking place 3 December for all ECHA Committee/WG members.

For upcoming WG meetings, an e-mail confirmation of registration will be sent to avoid multiple registrations.

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-IV-2019

The minutes were agreed without changes.

6. Discussion of Union authorisation applications

6.1 UA for product family containing propan-2-ol, PTs 2, 4 (eCA DE)

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

6.2 UA for product family containing CMIT/MIT, PT 6 (eCA FR)

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

6.3 UA for product family containing Peracetic acid, PT 2 (eCA UK)

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

6.4 UA for product family containing Hydrogen peroxide, PT 2 (eCA UK)

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

7. Discussion of active substances

7.1 Glyoxal, PT 19 (eCA FR)

The WG considered that the active substance is not an endocrine disruptor and that developmental toxicity has been adequately investigated. Based on the available

information, it was not possible to conclude on the carcinogenic potential of glyoxal. The WG agreed on a qualitative risk characterisation as no threshold could be set for the mutagenic effects based on the available information.

7.2 Sulfuryl fluoride, PTs 8, 18 (eCA SE)

The WG agreed on the need for in vivo follow-up on genotoxicity. The identified data gap for developmental neurotoxicity can be filled by a study or an assessment factor. Before requesting further information on ED properties, the eCA was requested to complement the assessment with information from open literature and by presenting the lines of evidence for each modality.

7.3 Chlorophene – revised assessment, PT 2 (eCA NO)

The WG agreed with the revised values for $AEL_{medium\text{-}term}$, $AEL_{long\text{-}term}$ and ADI proposed by the eCA.

7.4 Silver containing active substances – need for further information regarding carcinogenicity, PTs 1, 2, 4, 5, 6, 7, 9, 10, 11 (eCA SE)

The WG supported the eCA proposal to request a combined chronic toxicity/carcinogenicity study (OECD TG 453).

8. Technical and guidance related issues

8.1 Update on guidance development

SECR presented the current status of guidance documents. 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.

8.2 HEAdhoc: Update to HEEG Opinion 15 on antifouling paints

The WG agreed on the document, except for the value of actual hand exposure for professional brush/roller that will be discussed further within HEAdhoc. The agreed parts of the document will be published in the HEAdhoc website.

9. Any other business

9.1 Other information & lessons learned

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

Endocrine disruption (ED)

In the ED Expert Group taking place on 3 December 2019, two biocidal active substances will be discussed: Propiconazole (eCA FI) and Alpha-chloralose (eCA PL).

SECR informed that the ED Expert Group meetings for 2020 are provisionally scheduled as follows:

- 7-9 April
- 29 September - 1 October
- 17-19 November

Active substance action plan

As follow-up from the survey on the Review Programme and active substance workshop (February 2019), an action plan has been drafted and will be presented at the 86th CA meeting. The document proposes actions for ECHA, MSs and COM to speed up the Review Programme.These actions include:

- Actions to support the eCA evaluation
- Actions to improve the capacity building in the eCAs
- Streamlining the peer review

Next WG meetings

SECR informed of the provisional timing of the next meetings:

- 23 March – 3 April 2020 (dates to be confirmed, expected to be physical)

ECHA is moving

The agency will be closed 21 December 2019 – 6 January 2020 as all functions are moved to the new premises. The agency will open in the new premises on 7 January 2020.

The new address is Telakkakatu 6, Helsinki. The mailing address will not change (P.O. Box 400, FI-00121 Helsinki, Finland).

Annex 1

Human Health WG attendees

Core members
MIKOLAS Jan (CZ)
MEYER Jessica – alternate (DE)
NIKOLOPOULOU Dimitra (EL)
TERUEL Cristina (ES)
LORI Julia (FR)
BREEN Alan – alternate (IE)
BOS Carina (NL)
Rapporteurs
BOITIER Caroline (FR)
FRYDENLUND Jorid (NO)
LERJEVIK Ing-Marie (SE)
GRAY Anne (UK)
Flexible members
HAUZENBERGER Ingrid (AT)
HOUAMED Anis (BE)
GORTEMAN Jinne (BE)
DOLEZELOVA Katsiaryna (CZ)
GOTTLOB Kathrin (DE)
RIME Soyub (DE)
BOYE PETERSEN Annika (DK)
KÄOSAAR Sandra (EE)
HÄMÄLAINEN Anna-Maija (FI)
HYVÄRINEN Tuija (FI)
DEKOVI Edlira (IT)
GAUSTAD Astrid (NO)
GÓRECKI Roman (PL)
BIRGANDER Pernilla (SE)
LESER Vladka (SI)
OLHA Roman (SK)
ECHA Staff
AIRAKSINEN Antero (Chair)
DAMSTEN Micaela
RUGGERI Laura
PAPADAKI Paschalina
ANTAL Diana
ESTEVAN MARTINEZ Carmen
VASILEVA Katya
FRANKEN Stefan
HONKA Anni/SCHAKIR Yasmin
Applicants
Schuelke
Fraunhofer
Contec
BASF
Exponent
Lanxess
Knoell
ERM
Stakeholders
KASURINEN Ossi (CEFIC)
Advisors
BELLINGARD Valérie (FR)
KIRKEGAARD Maja (DK)
SWEDMARK Stellan (SE)