Final minutes of the Working Group meeting IV in 2020

Analytical Methods and Physico-Chemical Properties

(Meeting date: 17 November 2020 – WebEx meeting)

15 March 2021

1. Welcome and apologies

The meeting was a WebEx-meeting. The Chair welcomed the participants of the working group meeting. CEFIC was present at the meeting as an accredited stakeholder organisation (ASO) with one representative. The applicant SOPURA was invited to the meeting as an observer for their Union Authorisation application.

Participants of the working group were informed that the meeting is recorded, but solely for drafting the minutes and that the recording will be destroyed after the agreement of the minutes. The recording will not be 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).

The following items were added to the agenda:

- Acceptance of 5-batch data
- Storage stability tests for a Union Authorisation
- Redefinition of an in situ generated active substance
- Formulation requirements for product authorisation

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 III 2020

The working group members provided three comments on the draft minutes of WG III 2020.

The modifications were presented and agreed. The Chair informed that the document 'Definitions of the functions of co-formulants' has been revised according to the discussion at WG III 2020 and the final version will be forwarded to the coordination group (CG). No further comments were expressed at the meeting. The minutes of the working group meeting III in 2020 were agreed by the working group members.

6. Discussion of Union authorisations

6.1. Union authorisation for product family containing peracetic acid PT 02, 03, 04, 05 – eCA: BE

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

7. Any other business

7.1. Acceptance of 5-batch data

For the evaluation of an active substance the eCA explained that 5-batch analyses were received but not all parameters were determined on the same batches. In the first determination, only the impurities were analysed. In the second determination, only the content of the active substance was determined. The applicant has proposed to determine all components together on only one new batch, rather than repeating the whole 5-batch analysis. The working group members rejected the applicant's proposal and agreed that a complete new 5-batch analysis including all parameters shall be requested in order to be consistent with Guidance on the BPR, Volume I and earlier cases.

7.2. Storage stability tests for a Union Authorisation

The eCA explained that the applicant has submitted a long term storage stability study which is conducted according to section 2.7 of the guidance from the Chemicals Regulation Decision of the UK Health and Safety Executive for ambient shelf-life testing and Plant Protection Products (UK-guidance, 2017 and 2019). According to this guidance, the temperature in the study should reflect the minimum and maximum temperatures likely to be experienced during storage in a warehouse, farm store or garden store for amateur products. The submitted study recorded temperature variations from 4-28 °C over a period of 2 years. Guidance on the BPR, Volume I states that the leading guideline for ambient storage stability studies is the GIFAP (CropLife International) monograph no. 17. According to the GIFAP monograph, the ambient storage study should be conducted at t ± 2 °C (t = 20 °C, 25 °C, 30 °C or ambient temperature/room temperature). The active substance content is demonstrated to be stable both during the ambient storage stability study and the accelerated storage stability study. However, the packaging materials showed slight paneling of the HDPE containers and discoloration of the lid of the metal container during the study. The eCA asked the working group members whether the study can be accepted, even with the significant temperature variations and damage to the packaging. It was agreed that the temperature variations would be acceptable, as Guidance on the BPR, Volume I does not state exclusively that only GIFAP (CropLife International) monograph no. 17 can be used, but rather that it is the leading guidance. It was also noted that the temperatures in the study represent more realistic storage conditions than a stable temperature. However, the result of the test was considered not acceptable since reactivity to the packaging material occurs. The applicant should be asked for a justification on the damage to the packaging. If no acceptable justification can be provided, the test or part of it may need to be repeated.

7.3. Redefinition of an in situ generated active substance

The eCA explained that they would like to have a preliminary discussion on the ongoing e-consultation of an in situ generated active substance. The eCA is assessing three different applications for approval for that active substance and based on the information received during the evaluation, they would propose to redefine the active substance. The eCA considers that this is supported by the analytical data (NMR and HR-ESI-MS) submitted by the applicant. Other member states considered that it must be taken into account that that the in situ active substance is generated as an aqueous solution where the constituents might be present as ions which are not isolated to build the corresponding salts . It was considered that including a counterion in the substance name will only add complexity without any added

value. It was suggested that a description of the generation process and the species formed can be included in the CAR, but in general the working group members were very hesitant to agree with a redefinition. The Chair stated that the e-consultation is still ongoing and therefore no conclusion is made for the time being.

7.4. Formulation requirements for product authorisation

It was discussed that, although not required under the BPR, information on the formulation process of biocidal products could be useful to provide a better understanding on e.g. the composition and the formulation chemistry of the biocidal products. For plant protection products, the formulation process is a data requirement. Some member states informed that they sometimes request this information from the applicant and it is often helpful for the evaluation. The Chair noted, it could be possible to include in the TAB a recommendation for applicants to submit this information.

7.5. Presentation on Interact Portal

A presentation on the new Interact Portal was provided by ECHA. New functionalities for meetings and collaboration will become available in March 2021. ECHA will offer training and support on the new functionalities.

Annex 1 - List of attendees registered for the meeting

Country	Members of WG
Austria	Colson Jerome
Austria	Ghobrial Michael
Belgium	Burmistrova Anastasia
Belgium	Dang Thy Minh-Dung
Belgium	Lepage Anne
Switzerland	Aeschbacher Michael
Switzerland	Courdouan Merz Amandine
Czech Republic	Vlasak Martin
Germany	Mühle Ulrike
Denmark	Erlingsson Natja
Denmark	Domino Katrine
Denmark	Jespersen Cindy
Estonia	Ilmarinen Kaja
Finland	Vuorensola Katariina
France	Weber Philippe
Italy	Cataldi Lucilla
Latvia	Igaune Ieva
The Netherlands	Huizing Tjaart-Jan
Norway	Stave Sekkenes Marianne
Poland	Huszał Sylwester
Poland	Horczyczak Anna
Slovenia	Velikonja Bolta Špela
Sweden	Alpe Mia
Sweden	Johansson Anh
Slovakia	Porubiak Michal

ECHA staff
Krebs Bernhard (Chair)
Glans Lotta
Matthes Jochen

Company	Agenda item	Observer
Sopura	6.1 Union authorisation for SOPUROXID family	Verschaeve Stefaan Vandenbrouk Tine

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

WG-IV-2020
Final minutes
18 March 2021

Minutes of Efficacy WG-IV-2020

24 and 26 November 2020

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 34th Efficacy Working Group (EFF WG) meeting and informed that this meeting is split into two separate days.

Participants were informed that the meeting would be recorded solely for the purposes of writing the minutes and that the recordings 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 was declared.

5. Minutes

DE and FR had sent comments on the EFF WG-III-2020 draft minutes. The revised minutes were agreed at the meeting.

6. Discussion of active substances – 24 November 2020

6.1. Early WG discussion on *Chrysanthemum cinerariaefolium* (eCA ES)

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

7. Discussion of Union Authorisations – 24 November 2020

7.1. UA for product family containing Peracetic acid (eCA BE)

There were two open points and three provisionally closed points, which were all opened for discussion during the meeting. All points were closed at the meeting. Please refer to the confidential minutes in the form of the discussion table for more details.

8. Technical and guidance related issues – 26 November 2020

8.1. Vol. II, Parts B+C – Appendix 4

Appendix 4, Overview of standards, test conditions and pass criteria (PT 1-5), was published for the first time at the EFF WG webpage in May 2016 and updated in March 2017. Subsequently it was updated for PT 5, and included in the main guidance Vol. II, Parts B+C in 2018. Shortly after the publication several corrections were proposed, and the Appendix has been under discussion during 2019 and 2020. Along with the last revision, where all changes agreed at the EFF WG had been implemented, ECHA had also revised Appendix 3 on test organisms.

Both appendices were discussed in this meeting, and the EFF WG agreed on the following:

- The introductions of Appendices 1, 3 and 4 will be updated to indicate that all of them should be read together, because of containing complementary information.

- According to the principle of the tiered approach for testing disinfectants, phase 2, step 1 suspension tests will be required for PT 2, PT 3 and PT 4 room disinfection / automated airborne enclosure disinfection uses.
- For clarity, PT 2 instrument disinfection will be separated into two tables, one presenting the requirements for instrument disinfection in the medical area, and another for the other areas of use.
- Appendix 3 will be amended to differentiate virucidal claim, limited spectrum virucidal claim, and claim against enveloped viruses, and test viruses will be updated accordingly. Porcine Parvovirus NADL2, required in EN 17122 and EN 17272, will be added to the test organisms.
- As Appendix 3 does not differentiate whether the listed test organisms should be tested in phase 2, step 1 tests or phase 2, step 2 tests, or both, it was agreed to amend the text in the main guidance to make it more clear which test organisms are relevant for which test.
- It was discussed whether Vaccinia virus should be replaced with Feline Coronavirus as the test organism for PT 3 claim against enveloped viruses for teat disinfection. Since, however, there is currently no EN phase 2, step 2 test for teat disinfectants, and the test organism in the PT 3 phase 2, step 1 test (EN 14675) is ECBO, it was agreed that Vaccinia virus will be indicated as the relevant test organism for the claim in question.
- For clarity PT 3 hard surfaces table will be divided into tables, one for non-porous and one for porous surfaces. For non-porous surfaces EN tests are required, whereas for porous surfaces DVG guidelines will be indicated as relevant phase 2, step 2 tests (except for bacteria, for which there is an EN 16437 phase 2, step 2 test for porous surfaces). The log reductions required in the DVG guidelines for yeasticidal and virucidal claims are still a subject of discussion in the EFF WG. DE will send a proposal to ECHA for updating Appendix 3 to correctly reflect the test organisms indicated in the DVG guidelines. Similarly, DE will cross-check whether the soiling required in the DVG tests is correctly reflected in Footnote 4 of Appendix 4.
- Footnote 19 will be amended to indicate that for PT 3 room disinfection other test temperatures than 10°C can be accepted if relevant.
- The maximum contact time does not need to respect that given in the respective EN standard, but Footnote 3 will be amended to state that a justification should be provided when a longer contact time is claimed.
- For soiling in PT 2 textile disinfection it was agreed that ECHA will implement TAB entry #9 on efficacy testing for textile disinfection into the main guidance text, and Footnote 4 on soiling will be amended accordingly.
- Appendix 3 will be amended to correctly indicate the relevant test organisms to claim activity against bacterial spores.

In addition, some other more detailed comments were discussed and agreed upon. ECHA informed that main text in the guidance related to disinfectants will be revised based on agreements reached for Appendix 4 (and Appendix 3), and the revised text will be sent for EFF WG commenting in February 2021. WG discussion is foreseen for WG-I-2021 in March.

8.2. TAB proposals

PT18 crack and crevice treatment

To demonstrate efficacy of a product applied by crack and crevice treatment a test protocol, including a designed furniture in test chamber, was proposed. In the proposed protocol the insects have the choice not to be in contact with the product to reach water and food sources or untreated shelter. The treated tiles of appropriate material according to the claim (porous/non-porous) are inserted into the designed furniture.

Generally, the proposal was supported by the EFF WG. Discussion was raised whether the product should be applied on the furniture or on separate tiles to ensure that the furniture can be used in several tests. This can also be left for the applicant to choose. It was noted

that the insects should be released into the chamber not on the treated furniture to allow them to choose to go to the furniture or to the untreated shelter. IND will send proposals on the test setups and discussion will be continued in March 2021.

Attractants in PT18 bait products

All sections of the currently developed PT19 chapter will contain a sub-section on the efficacy evaluation of attractants in PT18 bait products, referring to the requirements in the PT18 chapter. For some target species the requirements for assessing attractants in bait products are missing from the current PT18 guidance. The proposal was supported by the EFF WG. During the discussion it was raised a question which species are missing from the current guidance and whether proposed criteria, ≥ 90% mortality, would be applicable to all of them. It was decided that the final proposal can have separate entries for different species if needed. DE will prepare the final TAB proposal and it will be presented to the WG in the future meeting.

8.3. Certification of testing laboratories for disinfectant efficacy testing (DE)

DE presented a proposal in WG-III-2020, where the WG members asked for more time to consider/check the potential consequences of such a requirement. The revised proposal was now presented by DE and re-discussed by the EFF WG. The EFF WG agreed that a mandatory requirement for the testing laboratories to be accredited should not be added for the time being. It was noted that the EN standard methods themselves contain several validation steps. Some members also informed that they have received efficacy data of a good quality from laboratories which are not accredited. Given the current situation and the high demand for disinfectants, the EFF WG was of the opinion that further requirements for efficacy testing of disinfectants are not necessary.

9. AOB

9.1. Other information & lessons learned

ECHA informed about provisional dates of the next WG meeting and the preliminary plan of the discussion. Short information about current guidance update and foreseen future discussions was given. The Chair also announced the results of the survey conducted among the participants of the last meeting.

9.2. Preventive treatment against wasps – outcome of the e-consultation (closed session)

Please refer to the confidential minutes.

List of Attendees

Efficacy Working Group IV-2020

Core members		
ATTIG Isabelle (FR)		PEELMAN Natania (BE)
DUH Darja (SI)		RONCI Maria Beatrice (IT)
GIATROPOULOS Athanasios (EL)		RUSCONI Manuel (CH)
HAMEL Darka (HR)		RYDMAN Elina (FI)
JANSEN Irina – alternate (DE)		WARMERDAM Sonja (NL)
POULIS Joan (NL)		WIGGERS Hanneke (NL)
ZUTZ Christoph (AT)		ÅSLING Bengt (SE)
Flexible members		**ECHA Staff**
BALDASSARRI Lucilla (IT)		SZYMANKIEWICZ Katarzyna (Chair)
BURMISTROVA Anastasia (BE)		PRIHA Outi
CLEYTON JØRGENSEN Charlotte (DK)		RAULIO Mari
DANADAIOVA Emese (SK)		KREBS Bernhard
DOLEŽELOVÁ Katsiaryna (CZ)		VAN GALEN Joost
DONZE Gerard (CH)		HONKA Anni
FISCHER Juliane (DE)		**Applicants**
FRANK Ulrike (SE)		Exponent
GRÜNIG David (CH)		Sopura
ILMARINEN Kaja (EE)		**Rapporteur**
JUSZCZUK Marek (PL)		GONZÁLEZ MÁRQUEZ Luisa (ES) BPC
KRÜGER Martin (DE)		**Advisor**
LEPAGE Anne (BE)		PORTELA Cristina (ES)
LYNCH Helen (IE)		**Stakeholders**
MAGNER Jörgen (SE)		GARMENDIA Irantzu (EBPF)
MALMGREN Birgitta (SE)		BERNARD Jennifer (expert)
MEIER Margrith (CH)		STEINHAUER Katrin (expert)
MEZULE Linda (LV)		THOM Ellen (expert)
NIEMINEN Timo (FI)		THEELEN Meredith (expert/AISE)
PECINKOVA Martina (CZ)		MORENO Mara (expert/AISE)

Environment WG-IV-2020

Final minutes

5 April 2021

Minutes of Environment WG-IV-2020

18-19 November 2020

Meetings of the Environmental Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 47 participants present, of which 8 were core members, 28 flexible members, 1 rapporteur and 4 adviser. Three representatives from accredited stakeholder organisation were 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.

5. Agreement of the draft minutes from WG-III-2020

The minutes were agreed without further discussion.

6. Discussion on active substances

6.1/6.2 ED assessment: Sulphur dioxide generated from sulphur by combustion - PT 4 / Sulfur dioxide released from sodium metabisulfite - PT 9 (DE)

The waiving of further data for non-target organisms was discussed and concluded. The case can proceed to the BPC.

Actions:

- **SECR** to consider organising a workshop to discuss the experience build so far (ED assessment, waiving)

6.3 Medetomidine e-consultation on PT 21 data requirements (renewal) - PT 21 (NO)

Two questions previously discussed via an e-consultation where presented and the follow up was further discussed.

WG members were requested to express their interest to lead or contribute to an expert group on new test requirements

Volunteers identified to contribute: SE (Johan), FR (Anne + other experts), DE (Sacha), NO (Marit), ECHA

No member has volunteered to take the lead, but it can be further explored, alternatively it should be discussed with CEPE if they could take the lead. CEFIC will explore if there is any expert that can contribute.

On the question what the exact scope of the expert group should be, it was noted that the scope should be limited and should respond to the questions raised at a.s. approval stage.

Actions:

- **SECR** To initiate the kick-off meeting and to contact CEPE to check their availabilities.

6.4 Early WG: PNEC aquatic for benzyl alcohol – PT 6 (NL)

One point regarding the derivation of the PNECaqua was discussed and concluded.

7. Discussion of Union Authorisation cases

7.1 UA for product family containing peracetic acid - PT 2, 3, 4, 5 (BE)

One point regarding the worst-case values to be used for the exposure scenarios was discussed and agreed. The item was further taken up in a more general way under item 7.3.

7.2 Early WG: UA for a product containing cyromazine (CH)

Ten points regarding the exposure assessment were discussed and agreed. The eCA will revise the assessment and some item will be confirmed when the case enters the peer review phase.

Actions:

- **SECR** to prepare for several emission scenarios TAB entries after the scenarios are finally agreed during peer review.

7.3 General discussion: worst case values for exposure scenarios (BE/SECR)

The WG agreed that for the equilibrium PAA/HP the highest in-use concentration should be used for the risk assessment, independent from the equilibrium ratio.

8. AOB

8.1 Overview on guidance (SECR)

SECR presented the status on guidance development and issues identified for the AHEE. Updates from WG members before the meeting have been included in the overview.

8.2 Conclusions of AHEE-5 follow ups (SECR)

For the points noted below, a follow up with defined participants was agreed at AHEE-5, since the items could not be closed.

AHEE-5 item AP5.2 – Open PT 18 TEG items for AHEE agreement

Item 17: Can the treatment of bedbugs be entirely evaluated with the classical barrier treatment scenario (changed following conclusion on item 14) only or should it be cumulated with a classic scenario in crack and crevices (or other)? (POINT 6)

AHEE-5 conclusion: As a worst-case approach, the classical barrier treatment according to the ESD taking into account the worst case cleaning efficiency (depending on the way of application) should be used for the time being.

To be further clarified in a follow up: Which FCE should be used and which scenario(s) should be used to assess bed bug treatment (barrier/cracks and crevices, spot treatment). Can the assessment be reduced to the intended use or should a holistic assessment always take place?

Conclusion WG-IV-2020:

If a surface treatment takes place, an FCE of 0.5 should be used, if a treatment in cracks and crevices takes place, an FCE of 0.25 should be used. The WG agreed on the noted default values for FCE, providing that spray application takes place.

No further default values for FCEs were considered necessary.

The classical barrier treatment should be calculated as default worst case scenario unless specified otherwise in the use description.

If it is detailed in the use description that more limited areas are treated and this can be justified with efficacy evaluation, a deviation from the default scenario is possible.

AHEE-5 item AP5.4 – Proposal for updates of the ESD for PT 5 (revised and new emission scenarios)

Point 2.2: Is the applicant proposal regarding the amount of water that is spilled (56.1%) acceptable or is a worst-case approach similar to another substance assessed in PT 5 (100% emission due to both spillage and urine without accumulation in animal bodies) preferable?

No conclusion was drawn at AHEE-5, in the following further background on the item is provided (copy from the original document prepared by NL for AHEE-5):

NL proposal to the WG: *The studies of Li and Torrey only investigated how to decrease the water wastage by pigs, but did not investigate whether a substance (e.g. Ag) going into the pig will stay in the pig or is removed by urine or faeces. Thus no mass balance can be made. Following the proposals these studies would be not useful. Additionally in the human health section no ADME studies were included, so no refinement options are possible. Therefore the proposal is to use the default emission factors to manure/slurry ranging between 0.8 and 0.9 depending on the stable and animal type.*

NL proposed conclusion: *Apply the default values of 0.9. These values include both release via urine and spillage. Refinement is possible when the absence of the active substance in urine is demonstrated. The value is then 0.56, i.e. only emission due to spillage.*

Conclusion WG-IV-2020:

In a first tier, the default value of 0.9 is used (according to the reference provided by BE and according to the proposed conclusion from NL), which was also confirmed by FR. This value includes both release via urine and spillage. Refinement is possible when the absence of the active substance in urine is demonstrated: based on the submitted data NL proposes to apply 20% spillage

for cows and pigs (=> emission factor of 0.2), which is a realistic worst case in view of the data submitted by BE for cows, and the average of the range for pigs. For poultry, which are predominantly nipple drinkers, NL would propose 14.5% spillage, based on the data from DE (=> emission factor of 0.145).

Point 3: Is the proposed tank volume acceptable?

No conclusion was drawn at AHEE-5, the following scenario was proposed by NL following further information provided by the applicant:

Parameter	Nomenclature	Value	Unit	Origin
input				
Concentration in drinking water	C_{form}		$mg.L^{-1}$	S
Application interval	T_{int}		d	S
Number of water tanks	N_{tank}	231	-	D
Volume of the water tank	V_{tank}	50	L	D
Fraction of water tanks to which biocides are added	F_{tank}	0.5	-	D
Fraction of active substance disintegrated during or after application (before release to the sewer)	F_{dis}	0	-	D
Fraction released to the waste water	F_{water}	1	-	D
Output				
Local emission to waste water	$Elocal_{water}$		$kg.d^{-1}$	O
Calculations				
$$Elocal_{water} = C_{form} \cdot \frac{N_{tank}}{Tint} \cdot V_{tank} \cdot F_{tank} \cdot (1 - F_{dis}) \cdot F_{water} \cdot 10^{-6}$$				

Conclusion WG-IV-2020 on the updated scenario:

The WG agreed in principle on the above proposed scenario, only the default value for the fraction released to waste water should be increased to 1.

Action: NL to provide full scenarios that are proposed to be included in the TAB for all scenarios suggested, including a description of parameters and default values within three weeks after the WG meeting.

8.3 Use of the XETA assay in the ED assessment (SECR)

SECR presented the current status of discussion on the use of the XETA assay in the ED assessment.

9. AOB

9.1 Other information & lessons learned (SECR)

Lessons learned:

General:
In case of suggestion for revisions of existing emission scenarios or new emission scenarios, always provide full (revised/new) scenario in a table including input + output parameters for discussion.
Send proposals for deviation/revision of ESDs first to AHEE or ENV WG for assessment and agreement => agreement needs to be reported in the TAB before it can be applied case-specific

Summing up of tonnages of two applicants (included also in TAB):
- The eCA sums up the tonnages in confidential part of CAR which by no means should be shared with applicants
- The eCA further calculates in non-confidential CAR maximum tonnage that would still result in a safe use (PEC/PNEC is just below 1)
- In confidential part of the CAR this tonnage is compared to the sum of applicant's tonnage and a conclusion on a safe/non-safe use is drawn
- Only this conclusion (safe/non-safe use) is then reported in the non-confidential part of the CAR

Case-related e-mails to ECHA: For AS/UA case related e-mails, please always copy in the AS/UA mailboxes:

- biocides-active-substance@echa.europa.eu
- biocides-union-authorisation@echa.europa.eu

This will ensure that the dossier managers are up to date – although the issues can be directly dealt with by the ENV colleagues, the dossier manager needs to know what is happening and what is agreed

Other information:

Provisional timing of coming WG meetings:
- AHEE-6 is provisionally planned for 10-11 February 2021 => depending on availability of items for discussion (*post WG meeting note: since no items have been brought forward by AHEE members, the meeting will be scheduled at a later stage in 2021*)
- WG-I-2021 ENV session provisionally planned 24-26 March 2021 – dates to be confirmed!
- There is always a possibility of additional ("extraordinary") ad hoc WebEx meetings, if needed.

All meetings organised by ECHA will remain virtual at least until the end of June 2021, moving to virtual meetings on a more permanent basis is currently under discussion.

WG-III-2020 Feedback Survey:
Total number of respondents: 71 (MSCA representatives 85%, ASOs 4%, Applicants 11%)
- 71% found pace of virtual meetings similar to face-to-face (f2f) meetings
  - Slowdowns mainly due to technical problems
  - Same members speak & contribute as in f2f meetings
- For 96%, agenda contained adequate number of items per day
  - As many work from home, work day hours should be respected
- 95% of WG members and all ASOs felt that their views were taken appropiately into account
- Vast majority (70%) felt able to participate in discussion in same way as in f2f meetings
- Quality of discussions found similar (73%) as in f2f meetings, 22% experienced quality of discussion lower

  - Correct experts can more easily attend on single agenda items
  - Audio-only web conference limits non-verbal interaction, which is seen very important
  - Further discussions during breaks enhancing finiding an agreement missing
  - Some participants more difficult to understand due to bad audio connections
- 66% felt finding agreements similar, 21% more difficult
  - Body language (nodding etc.) missing, pre-/post discussions during breaks missing
  - Agree in chat to replace nodding?
- Remote meetings seen by 59% as sustainable way forward in the long run, by 41% in short term

Pro:	Contra:
Less travelling	WG cohesion lost
Efficient use of time	Not easy getting to know members (newcomers)
Better for environment	No informal lunch break discussions (including topics not on agenda)
Less costs (MS & ECHA)	56% see informal communication very important, 37 somewhat important
More experts can attend	

- Wishes:
  - at least 1 physical meeting per year
  - 50:50 ratio after Covid-19
  - use of webcams to make meetings more personal
- Shorter meeting days (more days in total) was clearly preferred (by 45%) over longer days (8%) - for 37% there was no preference
- In general, participants able to follow discussion well
  - 70% followed more than 80% of discussion
  - 11% experienced technical/audio issues, which were solved
  - three participants complained about bad audio quality
- Suggestions how to integrate new members and increase WGs' cohesion
  - Some f2f meetings, use of webcams to get faces to names
  - Virtual coffee/lunch breaks, bilateral chat functions, Whatsapp group for informal messages
  - Welcome guide for new members, new members introduce themselves

German scenario for inland water marinas:
It was developed for product authorisations in PT 21 in Germany - reflects realistic worst-case conditions in German inland water marinas and is published on the UBA webpage: https://www.umweltbundesamt.de/en/topics/chemicals/biocides/environmental-risk-assessment-of-antifouling

- Information on derivation of scenario as well as all relevant parameters: see report "German scenario for inland water marinas"
- Data required and adapted PT 21-Excel-Tools for all relevant PT 21 active substances: see data folder „German scenario for inland water marinas – data"
- Document answering some frequently asked questions: see „Authorisation and environmental risk assessment of biocidal antifouling products"

ED EG: The agendas and reports of the ED EG meetings are publicly available on the ECHA website on the ED EG page: https://echa.europa.eu/endocrine-disruptor-expert-group

In case of questions, consider contacting your country's ED EG member or the ED EG secretariat's functional mailbox ed_eg@echa.europa.eu.

BPC-37: EFF WG document:
Document: "Harmonized approach to determine a worst-case (or representative) test product for a disinfectant BPF". Usually only one core efficacy assessment will be performed for a BPF. The assessment is based on one worst-case test product, which is ideally an existing product of the family and or must be sufficiently close to the worst-case The document provides guidance:

- On determining a worst-case test product for efficacy assessment for disinfectant BPFs (PT 1-5)
- how bridging studies should be designed to substantiate the choice of the worst case test product composition.

9.2 New functionalities Interact portal (SECR)

SECR informed the WG about the new functionalities.

Appendices:

Appendix 1: List of participants

Core members:
- (DE) Daniel **FREIN –** rapporteur Sulfur dioxide PT4 and PT9
- (DE) Eleonora **PETERSOHN**
- (FR) Stéphanie **ALEXANDRE**
- (FR) Anne **STRACZEK**
- (FR) Jerome **LOZACH** - alternate
- (IE) Helena **JOYCE**
- (NL) Barry **MUIJS –** rapporteur Benzyl alcohol
- (SI) Petra **MURI**

Flexible members:

- Altmann Dominik (AT)
- Kantner Christian (AT)
- Kührer Lukas (AT)
- Brasseur Anne (BE)
- Ceusters Christiaan (BE)
- Heulens Bart (BE)
- A Marca Maria (CH)
- Gyalpo Tenzing (CH) – rapporteur cyromazine
- Sedlackova Viktorie (CZ)
- Michaelis Katja (DE)
- Wennermark Henrik (DK)
- Sulg Helen (EE)
- Martin Vallejo Myriam (ES)
- Ruiz Lopez Elena Fuensanta (ES)
- Hänninen Oskari (FI)
- Pasanen Jaana (FI)
- Penttinen Sari (FI)
- De Magistris Isabella (IT)
- Smit Els (NL)
- van Vlaardingen Peter (NL)
- Aamodt Solveig (NO)
- Espevik Randall Marit (NO) – rapporteur Medetomidine
- Haraldsen Terje (NO)
- Podlaska Agnieszka (PL)
- Rzodeczko Helena (PL)
- Hahlbeck Edda (PL)
- Persson Johan (SE)
- Molnarova Jana (SK)

Rapporteurs:

- Lepage Anne (BE) - UA - BP Family with PAA

Advisors:

- Aeschbacher Michael (CH) - cyromazine
- Villumsen Rasmus (DK)
- Jacob Stefanie (DE) - Sulfur dioxide PT4 and PT9
- Säll Liselott (SE)

ASOs:

- Garmendia Irantzu (CEFIC representative) – all agenda items except closed ones
- Mason Paul (CEFIC expert)
- Spang Guenter (Aqua Europa) – 8.1 Overview on guidance

ECHA chairs and experts

Human Health WG-IV-2020

Final minutes

19 March 2021

Minutes of Human Health WG-IV-2020

24-25 November 2020

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 48 members or advisers registered, of which 11 were (alternate) core members. Two stakeholder representatives and one expert were registered. Applicants were registered for their specific substance discussions. Two representatives from EFSA participated the discussion on agenda items 6.1 and 6.2.

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

2. Administrative issues

SECR informed that from WG-I-2021 onwards, the agenda and meeting documents will be shared via Interact. Training will be provided before this takes place, and for the first meeting both systems (S-CIRCABC and Interact) will be used.

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-III-2020

The minutes were agreed without further changes.

6. Discussion of active substances

6.1 Sulphur dioxide generated from sulphur by combustion, PT 4 (eCA DE)

6.2 Sulfur dioxide released from sodium metabisulfite, PT 9 (eCA DE)

These agenda items were discussed together.

The ED assessment was not agreed on, and it will need further revisions before it can be closed. Another discussion is expected to take place at WG-I-2021.

The reference values were agreed as proposed by the eCA.

7. Discussion of Union authorisation applications

7.1 UA for product family containing Peracetic acid, PTs 2, 3, 4, 5 (eCA BE)

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 guidance documents. The document is available in S-CIRCABC to members and associated stakeholder organisations.

8.2 Dermal absorption of rodenticides (closed session)

The document was not agreed on, but a revised version will be provided by DE with the intention of separating non-confidential proposals from any confidential information.

Please see also confidential minutes that are provided to MSCAs only.

9. Any other business

9.1 Other information & lessons learned

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

e-mails to ECHA Secretariat

SECR reminded to always copy in the functional mailboxes to ensure that the relevant persons including dossier managers are up to date. These mailboxes are as follows:

- For active substance issues: biocides-active-substance@echa.europa.eu
- For Union authorisation issues: biocides-union-authorisation@echa.europa.eu
- For WG organisation or any practical WG related issues: BPC-WGs@echa.europa.eu

Survey after WG-III-2020

SECR informed in detail of the survey that mostly concerned the virtual nature of the recent WG meetings. The feedback was overall very positive, and virtual meetings were seen as a viable way forward. The details are available in the presentation in S-CIRCABC to MSCAs and associated stakeholder organisations.

Next WG meetings

SECR informed of the provisional timing of the next meetings:

- 15-26 March 2021 (exact days to be established)
- 2-11 June 2021 (exact days to be established)

All meetings organised by ECHA will remain virtual at least until the end of June 2021.

9.2 Training session: in vitro methods and ToxCast in assessing endocrine disruption

SECR provided a training session on in vitro methods and ToxCast information in assessing ED properties. The presentation is available in S-CIRCABC to MSCAs and associated stakeholder organisations.

Annex 1

Human Health WG attendees

Core/Alternate members
MIKOLAS Jan (CZ)
HOLTHENRICH Dagmar (DE)
HERRMANN Kristin – Alternate (DE)
NIKOLOPOULOU Dimitra (EL)
TERUEL MUNOZ Cristina (ES)
AUBIN Aurelie – Alternate (FR)
LORI Julia (FR)
MAXIMILIEN Elisabeth (FR)
BREEN Alan – Alternate (IE)
BOS Carina (NL)
LEŠER Vladka (SI)
Rapporteurs
LEPAGE Anne (BE)
Flexible members
HAUZENBERGER Ingrid (AT)
HOELZL Christine (AT)
HERREMANS Yannick (BE)
GRÜNIG David (CH)
ROSSIER Nadine (CH)
SANS-PICHE Frederic (CH)
GOTTLOB Kathrin (DE)
RIME Soyub (DE)
ROITZSCH Michael (DE)
SCHNEIDER Heiko (DE)
BOYE PETERSEN Annika (DK)
HÄMÄLAINEN Anna-Maija (FI)
HYVÄRINEN Tuija (FI)
RYDMAN Elina (FI)
VÄLIMÄKI Elina (FI)
DEKOVI Edlira (IT)
ANDERSEN Hilde (NO)
FRYDENLUND Jorid (NO)
GAUSTAD Astrid (NO)
MIDTHAUG Hilde Karin (NO)
GORECKI Roman (PL)
LITENS KARLSSON Sabina (SE)
ČEBAŠEK Petra (SI)
ROMAN Olha (SK)
Advisors
MANI Orlando (CH)
KLUTZNY Saskia (DE)
KNEUER Carsten (DE)
GEBEL Thomas (DE)
THYEBORG LIND Helene (DK)
BELLINGARD Valerie (FR)
COLLIN Elodie (FR)
KOSE Serif (FR)
BORGES Teresa (PT)
ECHA Staff
AIRAKSINEN Antero
DAMSTEN Micaela
ESTEVAN MARTINEZ Carmen
FRANKEN Stefan
PAPADAKI Paschalina
RUGGERI Laura
VASILEVA Katya
SCHAKIR Yasmin
Applicants
Sopura
Afepasa
Micro-Pak
Experts
RINCON Ana Maria (EFSA)
TIRAMANI Manuela (EFSA)
Stakeholders
VAN BERLO Boris (CEFIC)
Expert:SPANG Günther/Aqua Europa (AP 8.1)